

### **REMARKS**

The present preliminary amendment is in response to the Notice of Non-Compliant Amendment (37 CFR 1.121) and is in further response to the Advisory Action mailed March 30, 2005, in which the allowed claims were specified as being Claims 1-9, 20-22, 24, 26, 34 and 49 and wherein it was stated that the specification and drawings should be amended.

In the Notice of Non-Compliant Amendment the Legal Instruments Examiner specified that each of the marked-up pages of drawings must say "Replacement Sheet" on them. This change has been made herein not only to Figure 5 which was submitted in the Applicants' Preliminary Amendment faxed on April 18, 2005, but also to all of the figures which accompanied Applicants' previous Amendment mailed February 15, 2005.

In the Notice of Non-Compliant Amendment the Legal Instruments Examiner also specified that the status identifier of the claims must be changed from "previously submitted" to --previously presented--. Applicants have done that herein.

In the Advisory Action the Examiner specified:

- (1) *That the specification and drawings should be amended to reflect corrections to the drawings including their renumbering;*

- (2) *That the amendment to the specification contains typographical errors; and*
- (3) *That the term "existing method" in the brief description of the drawings was not clear.*

In response, Applicants have corrected the typographical errors and have added the language --Prior Art-- to Figure 5 as set forth herein, thus overcoming Items (2) and (3). In addition, the legend --Prior Art-- has been added as well to Figures 6, 7, 8, 9, 10, 11, and 12 in lieu of "(The existing method)" for the sake of consistency.

With respect to Item (1) the undersigned attorney for Applicants held a telephone conference with the Examiner in which it was decided that no renumbering is needed. The undersigned attorney expresses his appreciation to the Examiner for holding the telephone discussion.

All changes are made for clarification and are based on the application and drawings as originally filed. It is respectfully submitted that no new matter is added.

Favorable reconsideration is respectfully requested.

**CONCLUSION**

In light of the above amendments and remarks, Applicants respectfully submit that the specification and all pending claims as currently presented are in condition for allowance.

Applicants respectfully request that a Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'T. Moga', with a long horizontal flourish extending to the right.

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Registration No. 34,881  
Attorney for Applicants

Dated: **May 25, 2005**

TTM/hs

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**Amendments to the Drawings:**

Figures 1, 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 26, 27, 28, 93, 94, 95, 97, 98, 100, 101, 102, 103, 104, 105, 106, 109, 110, 111, 112, 113, 114, and 115 have been amended as indicated on the attached sheets marked "Annotated Marked-Up Drawings." A clean set of these figures is included, each sheet being marked "Replacement Sheet."

Please note that original Figure 4 was cancelled in the amendment of February 15, 2005. New Figure 4 is taken from original Figure 3 which had two views. Now Figure 3 has only one view.

Please note also that amendments to all of these figures were previously submitted by Applicants in their response of February 15, 2005. Figure 5 was subsequently amended in Applicants' Preliminary Amendment sent to the USPTO on April 18, 2005, by facsimile. These drawings are being resubmitted herewith to indicate --Replacement Sheet--and --Annotated Marked-Up Drawings-- where appropriate.

Applicants respectfully submit that no new matter has been added by the amendments to the figures.



## ANNOTATED MARKED-UP DRAWINGS

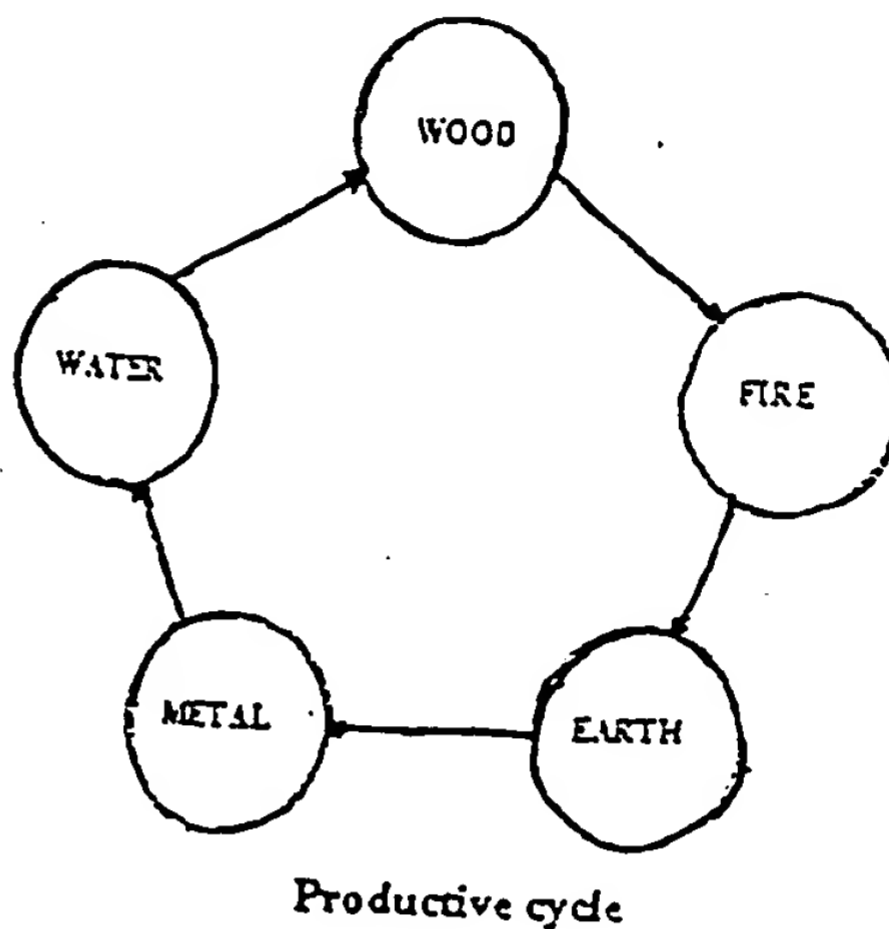


Figure A shows the element that helps the other element

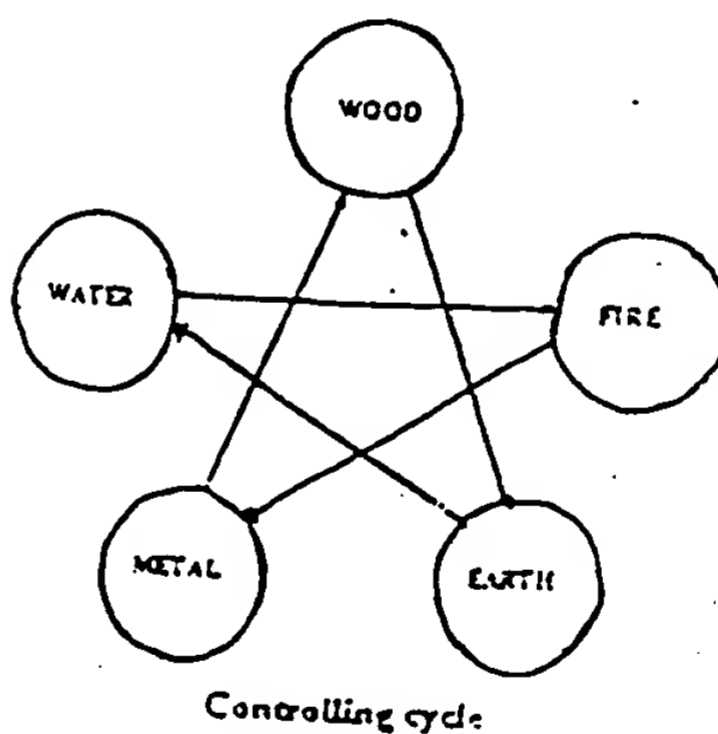


Figure B shows the element that controls the other element

~~Any imbalance (excess or deficiency) of one element leads to disturbance in other elements and becomes the root cause of a disease. The health of human body is achieved by managing and controlling the above elements in Chinese medicine. Most of the world traditional philosophies follow the same concept.~~

Figure 1

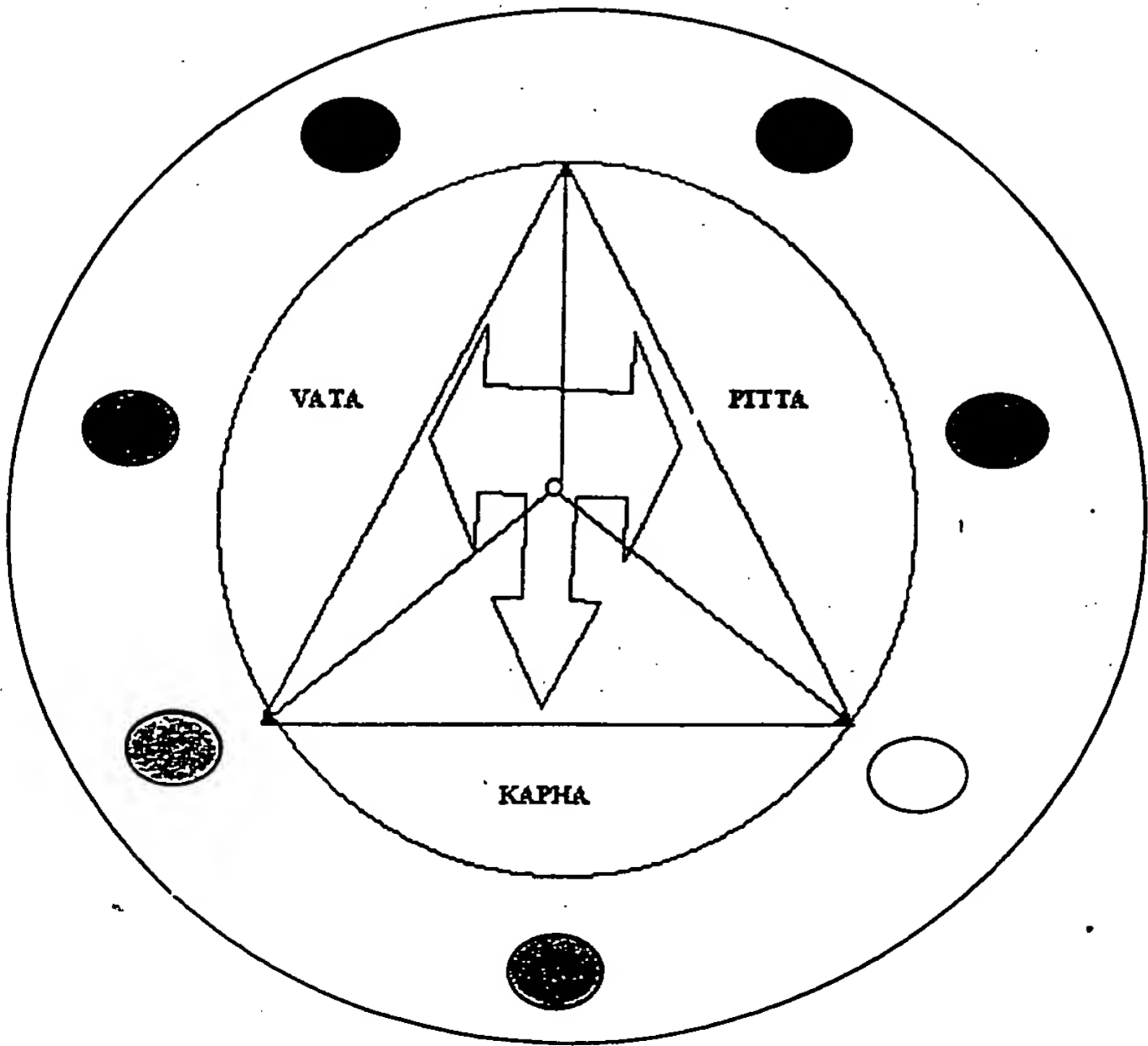
Prior Art

**ANNOTATED MARKED-UP DRAWINGS**

Figure 2  
Prior Art

~~Relation of colors with humors~~

VATA	KAPHA	PITTA



ANNOTATED MARKED-UP DRAWINGS

~~Figure 3~~

Figure 3

~~THE SHILAJIT EXAMPLE~~

Figure 4

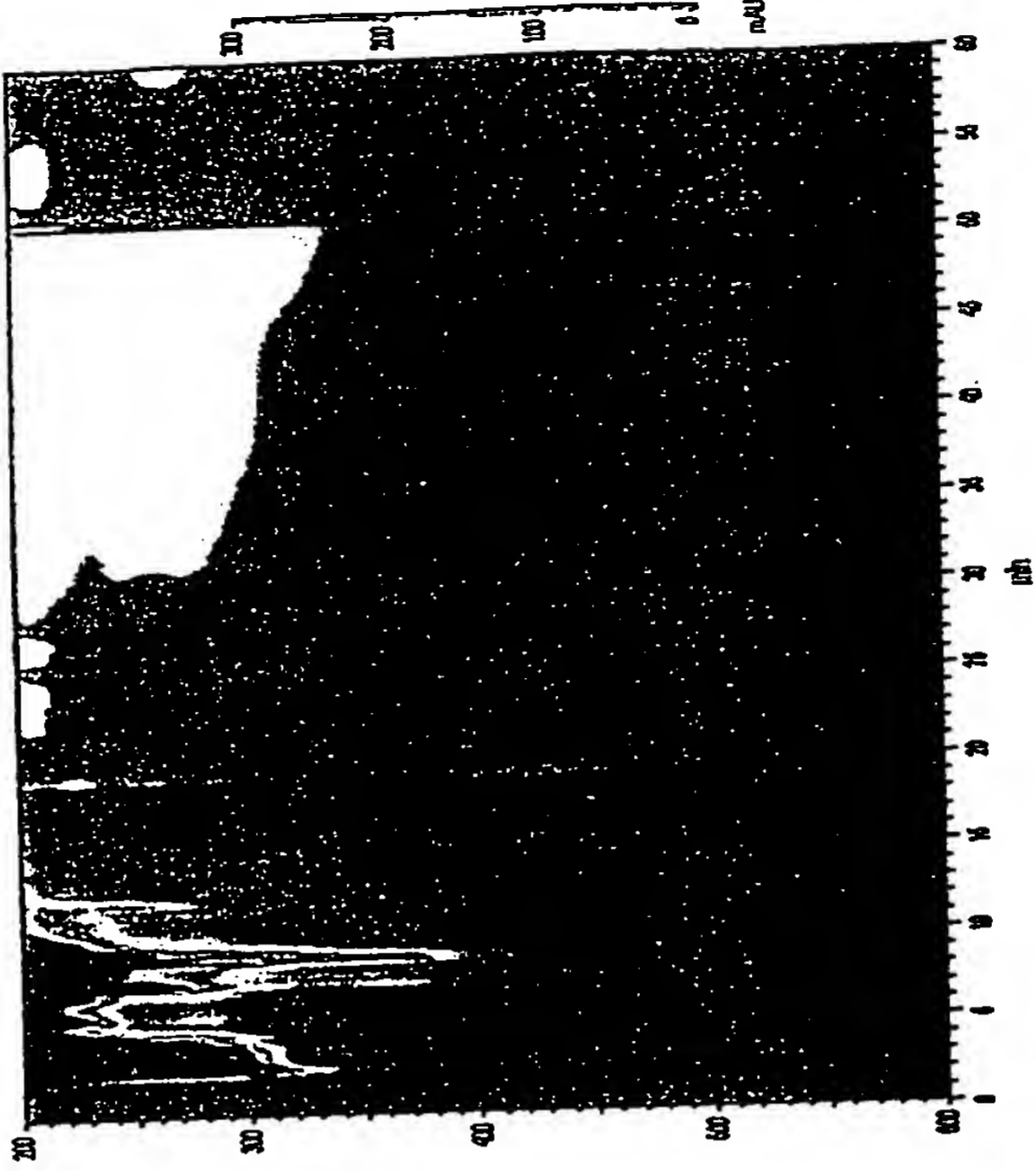
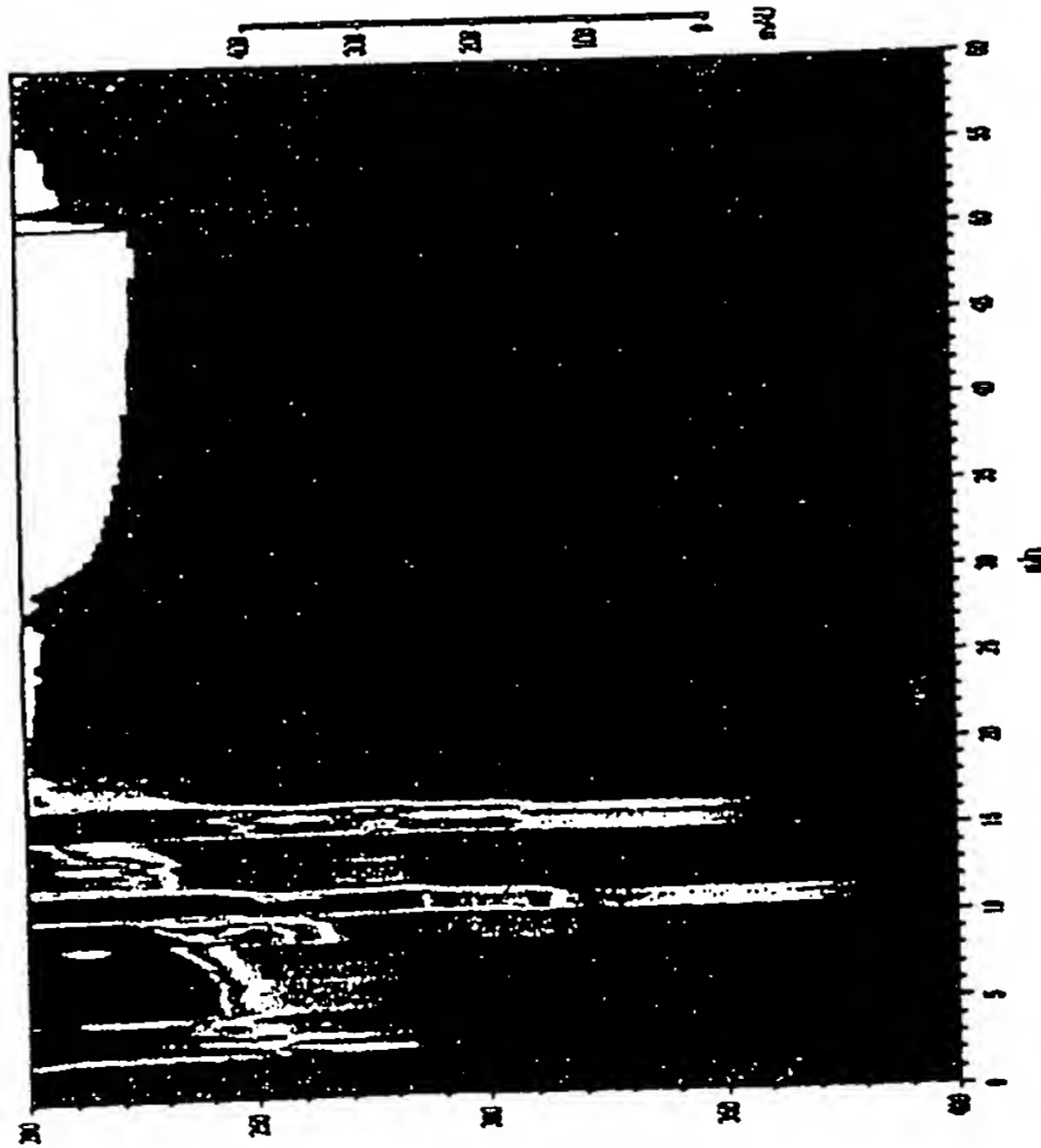
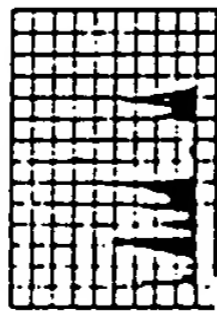


Figure 4

Herbal formulations with the same ingredients may differ substantially in safety and efficacy depending on the quality and processing of the herbs. Careful selection of herbs, stringent quality control and Chromatographic fingerprinting ensure that the final product delivers the same benefits that have been proven in clinical studies.

Each **Ayurvedic CONCEPTS** formula represents the results of subjecting ancient Ayurvedic knowledge to rigorous modern research and scientific analysis. These products are manufactured according to the rigid standards of modern pharmaceutical technology.



Store in a cool, dry place.  
Keep out of the reach of children.

Research expertise by:  
**THE HIMALAYA DRUG CO.**  
MUMBAI, BANGALORE - 562 123 (INDIA)  
Enriching Ayurveda Through Research Since 1930

ID-CC-DH-11-X0701

# Ayurvedic CONCEPTS



## Daily Health Capsules

Antistressor • Rejuvenator  
Amla • Licorice  
• Natural Zinc

60 CAPSULES

### Each capsule contains:

Pdts.	
Amalaki	90 mg
Garijara	90 mg
Yashad bhasma	1.94 mg
Exts.	
Amra	120 mg
Yashu-modhu	25 mg
Lavanga	25 mg
Draksha	10.50 mg
Oil	
Godhuma	17.56 mg

Dosage:  
2 capsules twice a day.

Natural products provide gradual but long-lasting results. Allow several weeks for full benefits.

Mfg. Lic. No.: AIJS-83

M.R.P.: Rs. 60.00  
(Incl. of all taxes)

Exp.: 3 yrs. from date of Mfg.

B.No.: 90702

Mfd.: July 99

Made in India by:

**THE HIMALAYA DRUG CO.**  
MUMBAI, BANGALORE - 562 123 (INDIA)

## ANNOTATED MARKED-UP DRAWINGS

Relieves stress, mental fatigue, Rises a healthy equilibrium.

Stress has become part of life today.

Continued stress disrupts the immune system leading to chronic fatigue, hypertension. Pollution and chemicals cause oxidative damage to the body by the release of free radicals, thereby disturbing normal body functions.

Daily Health capsules are non-sedating rich in anti-oxidant vitamins in the form of Amra and Garijara (vit.A), Amalaki (Amla) (vit.C), and Lavanga (Clove), Draksha (Grapes) and Godhuma (Wheatgerm) oil (vit.E). Yashu-modhu (Licorice) and Yashad bhasma (Nuts Zinc) are excellent immune-stimulants that bolster the body's defence mechanism keeping you fit and healthy.

Clinical trials on the product have proved it to be beneficial in the treatment of stress of various origins.

Ayurvedic Proprietary Medicine.

Completely safe. Non-toxic.

**NON-SEDATING.**

The chromatographic fingerprint does not give any clear information about the polarity and conjugative properties of the constituents.

# CHROMATOGRAMS OF A COMMERCIAL TURMERIC POWDER AT

## AT DIFFERENT WAVELENGTHS

(The existing method)

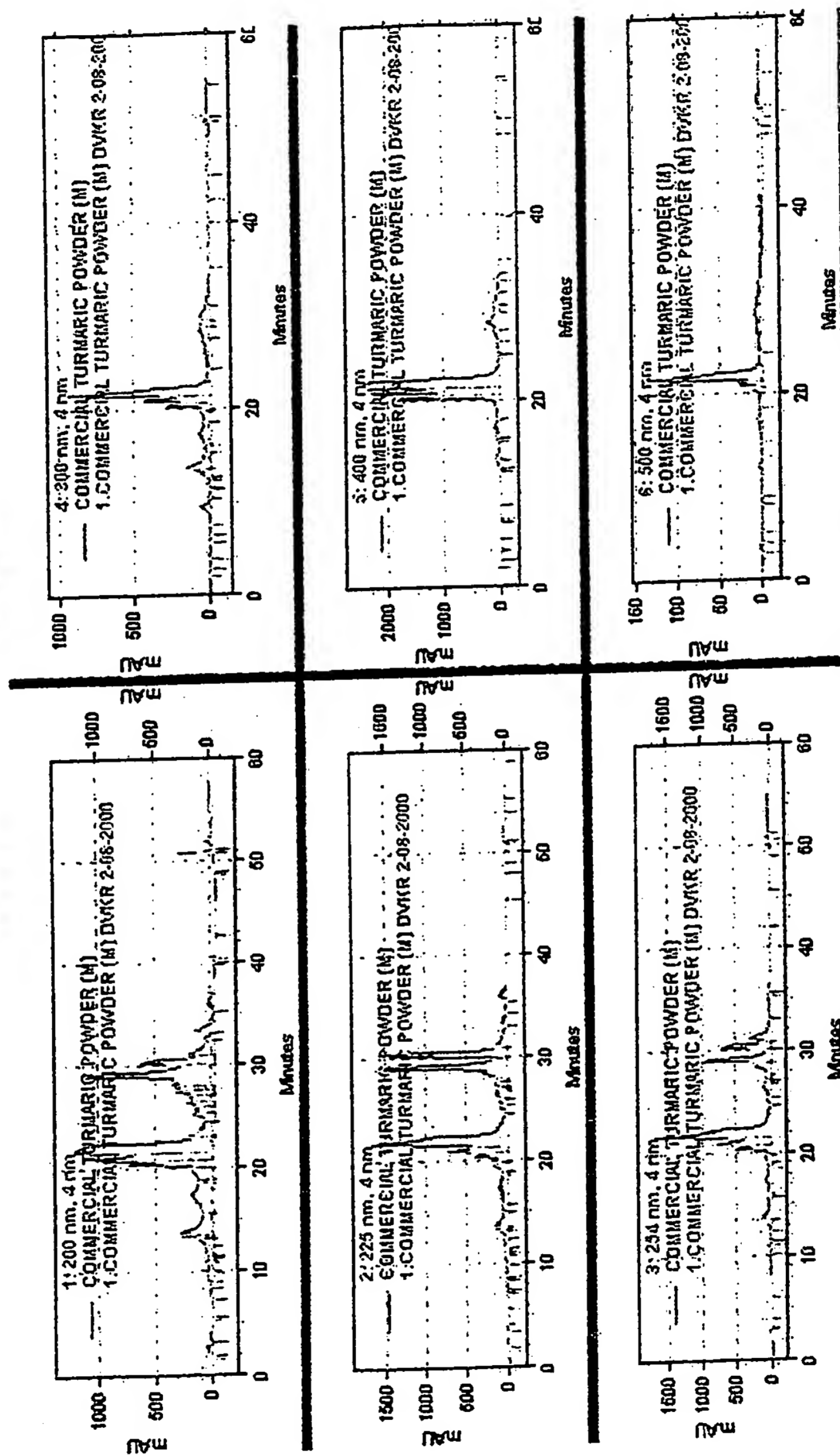


Figure 5

CHROMATOGRAMS OF A FURAZOLIDINE MEDICINE

AT DIFFERENT WAVELENGTHS

(The existing method)

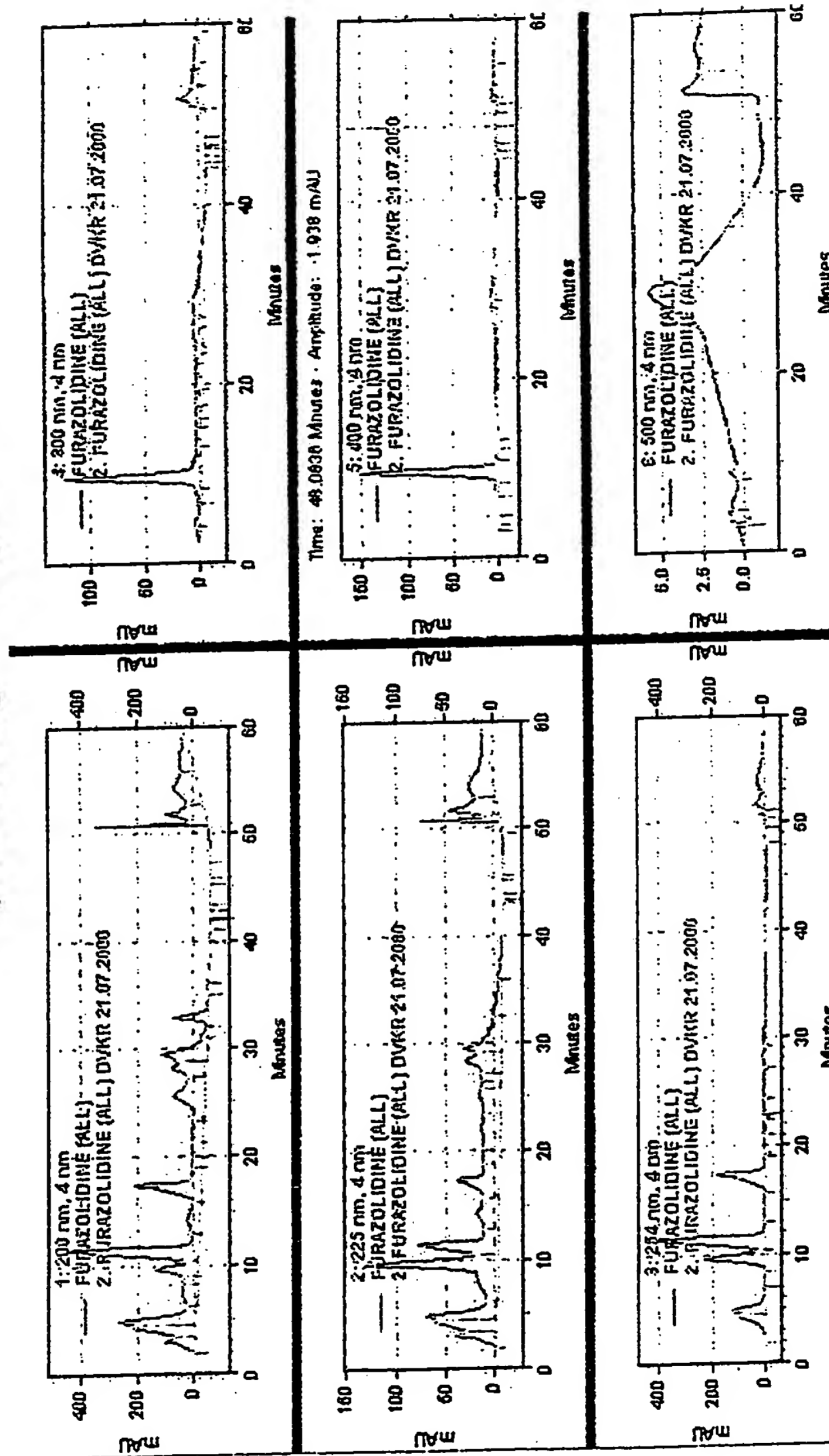


Figure 6

# CHROMATOGRAMS OF A HERBAL FORMULATION

## KRIMI KUTARA RASA

### AT DIFFERENT WAVELENGTHS

(The existing method)

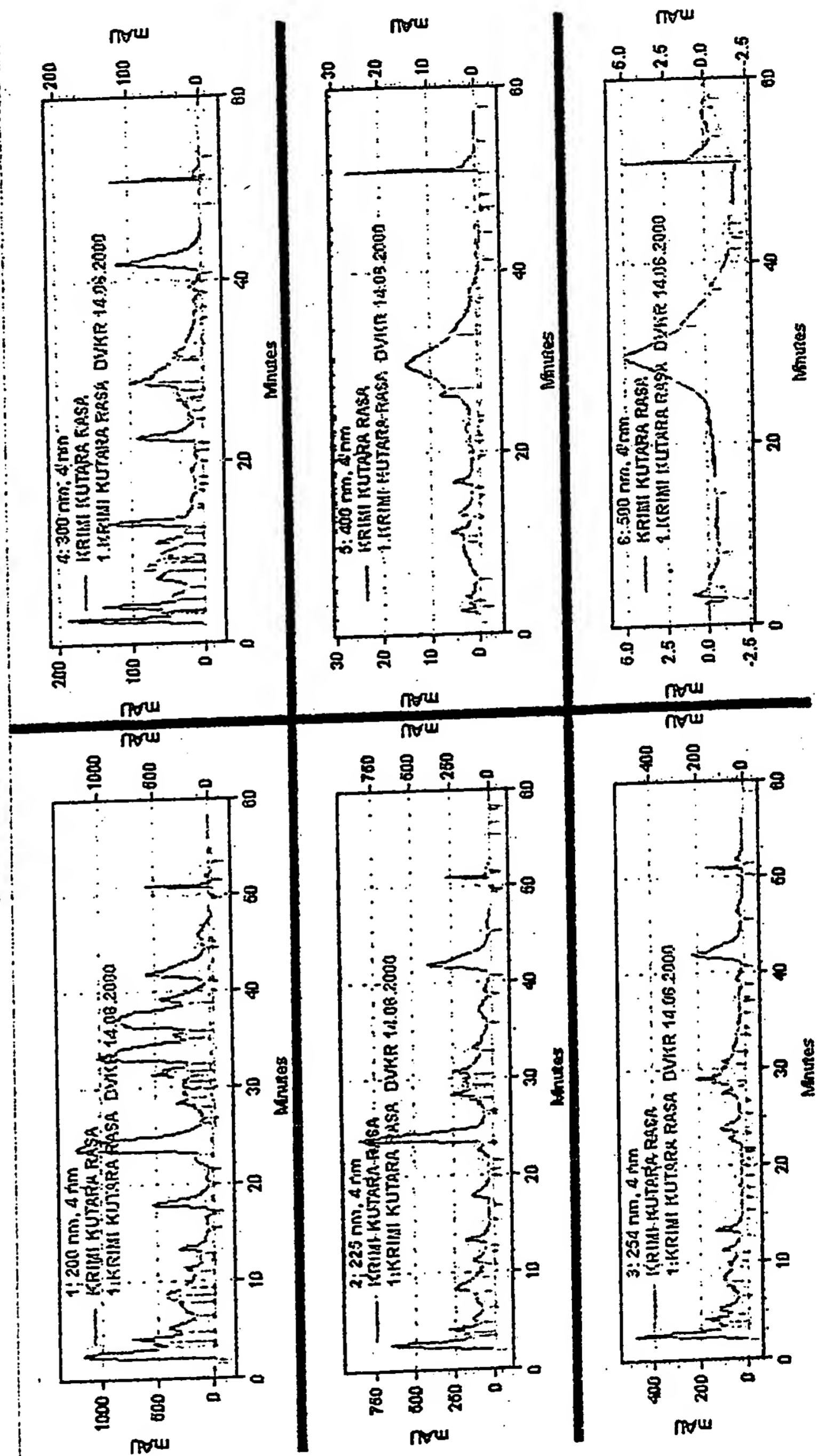


Figure 7

# CHROMATOGRAMS OF A HERBOMINERAL MEDICINE

## SHILAJIT (GOOD BY EFFICACY)

### AT DIFFERENT WAVELENGTHS

(The existing method)

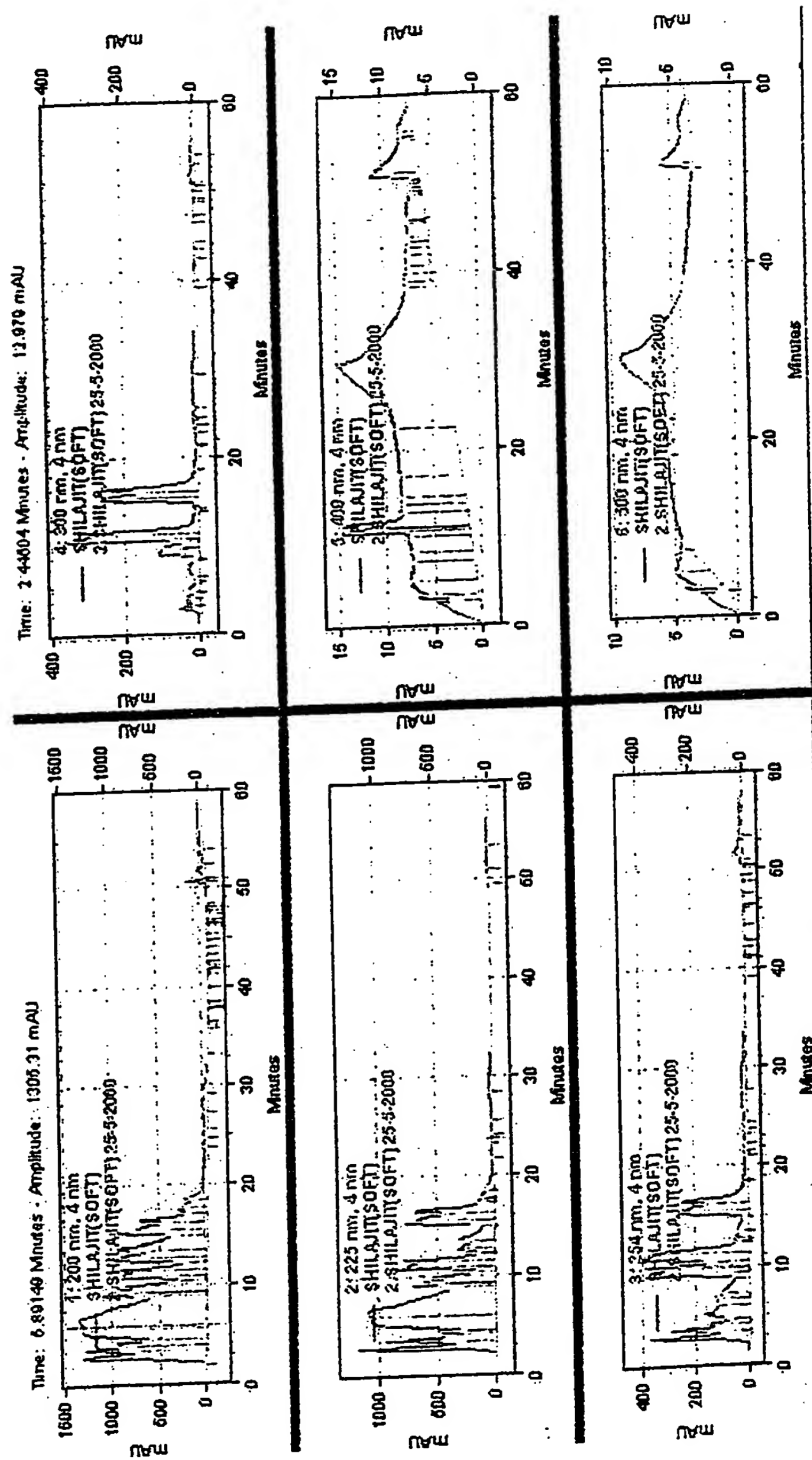


Figure 8

~~CHROMATOGRAMS OF A HERBOMINERAL MEDICINE~~

~~SHILAJIT (POOR BY EFFICACY)~~

~~AT DIFFERENT WAVELENGTHS~~

~~(The existing method)~~

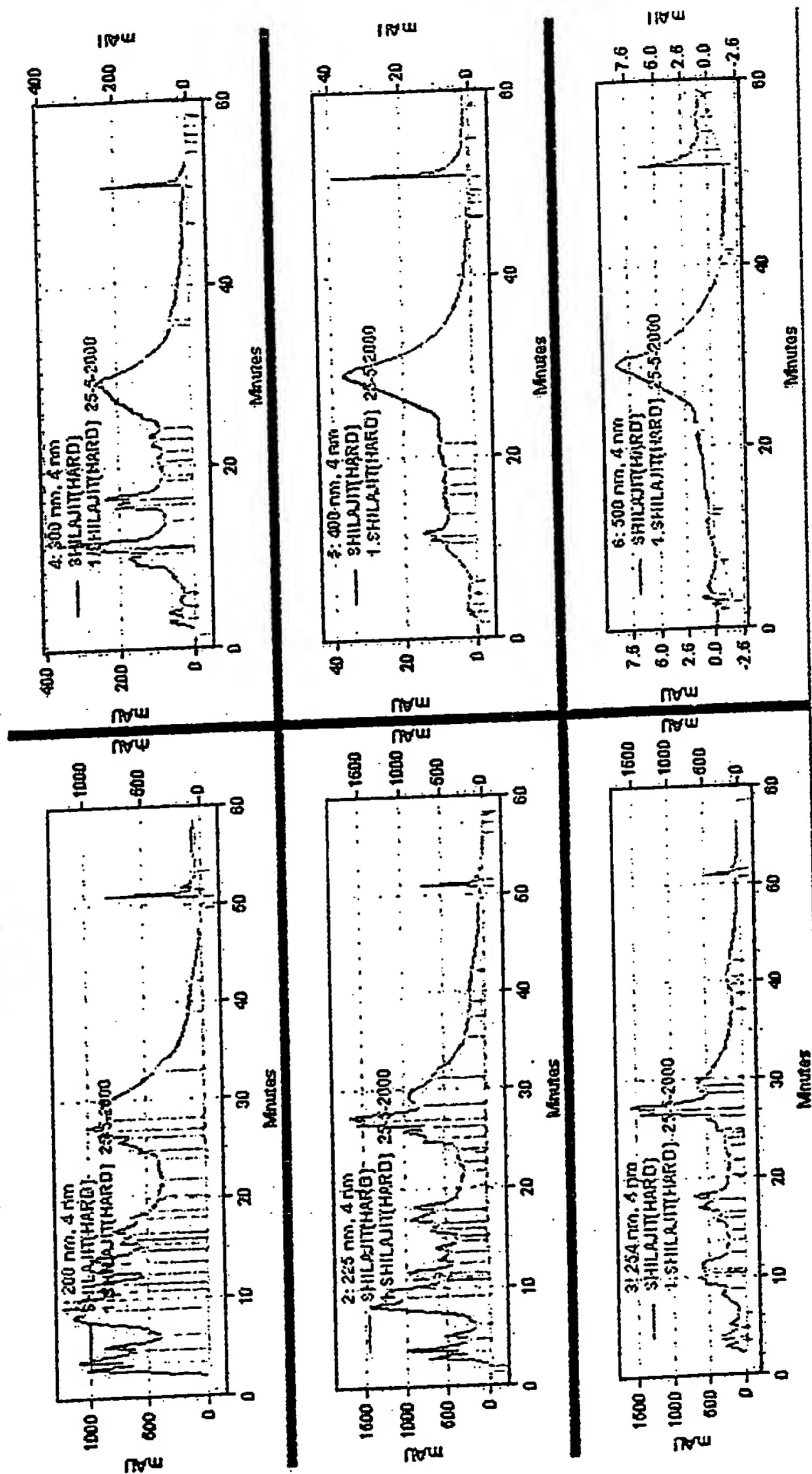


Figure 9

# CHROMATOGRAMS OF A HERBAL FORMULATION

SURYAVARTI

AT DIFFERENT WAVELENGTHS

(The existing method)

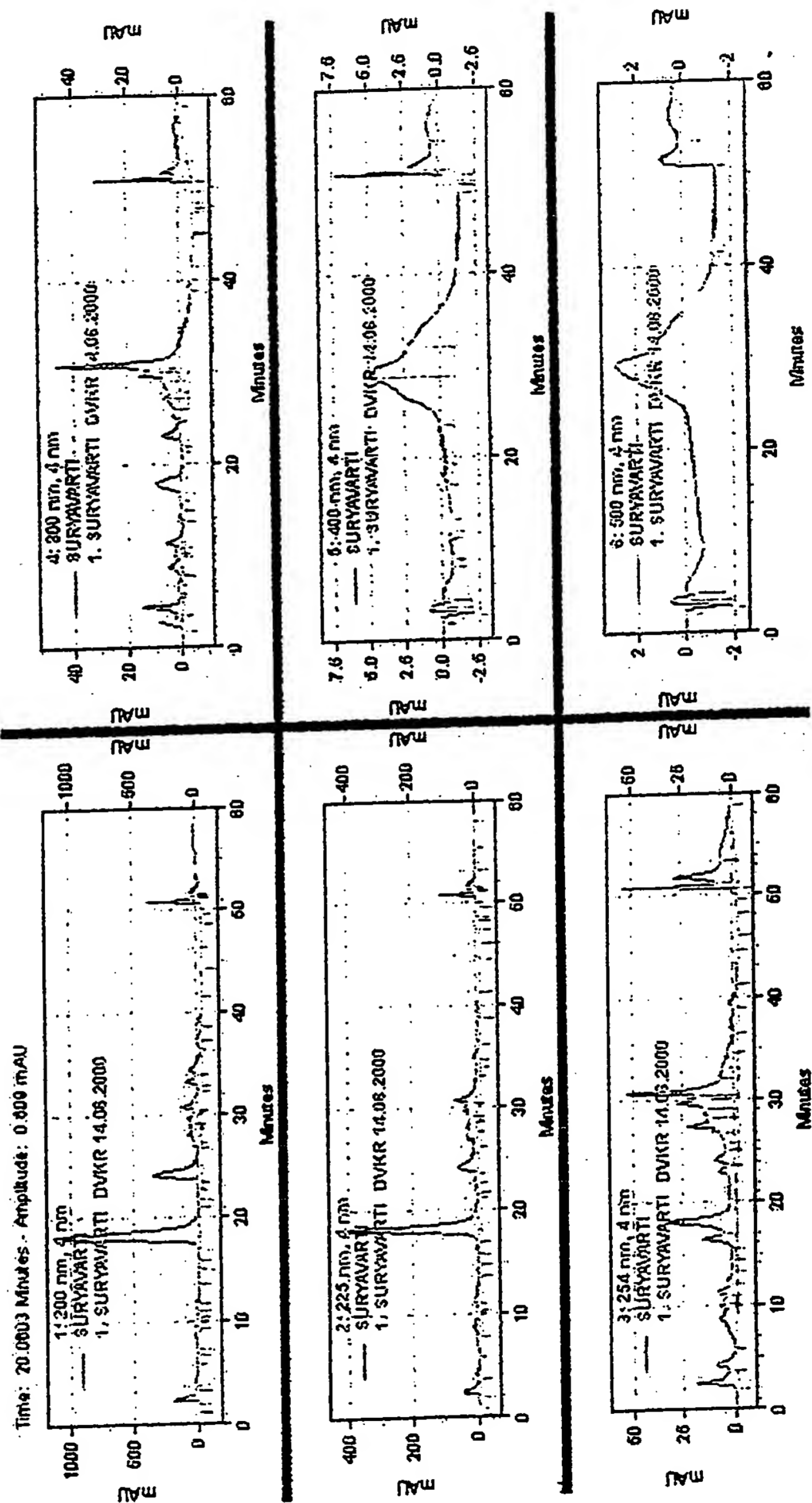


Figure 10

# CHROMATOGRAMS OF A HERBAL FOOD PRODUCT

TEA

## AT DIFFERENT WAVELENGTHS

(The existing method)

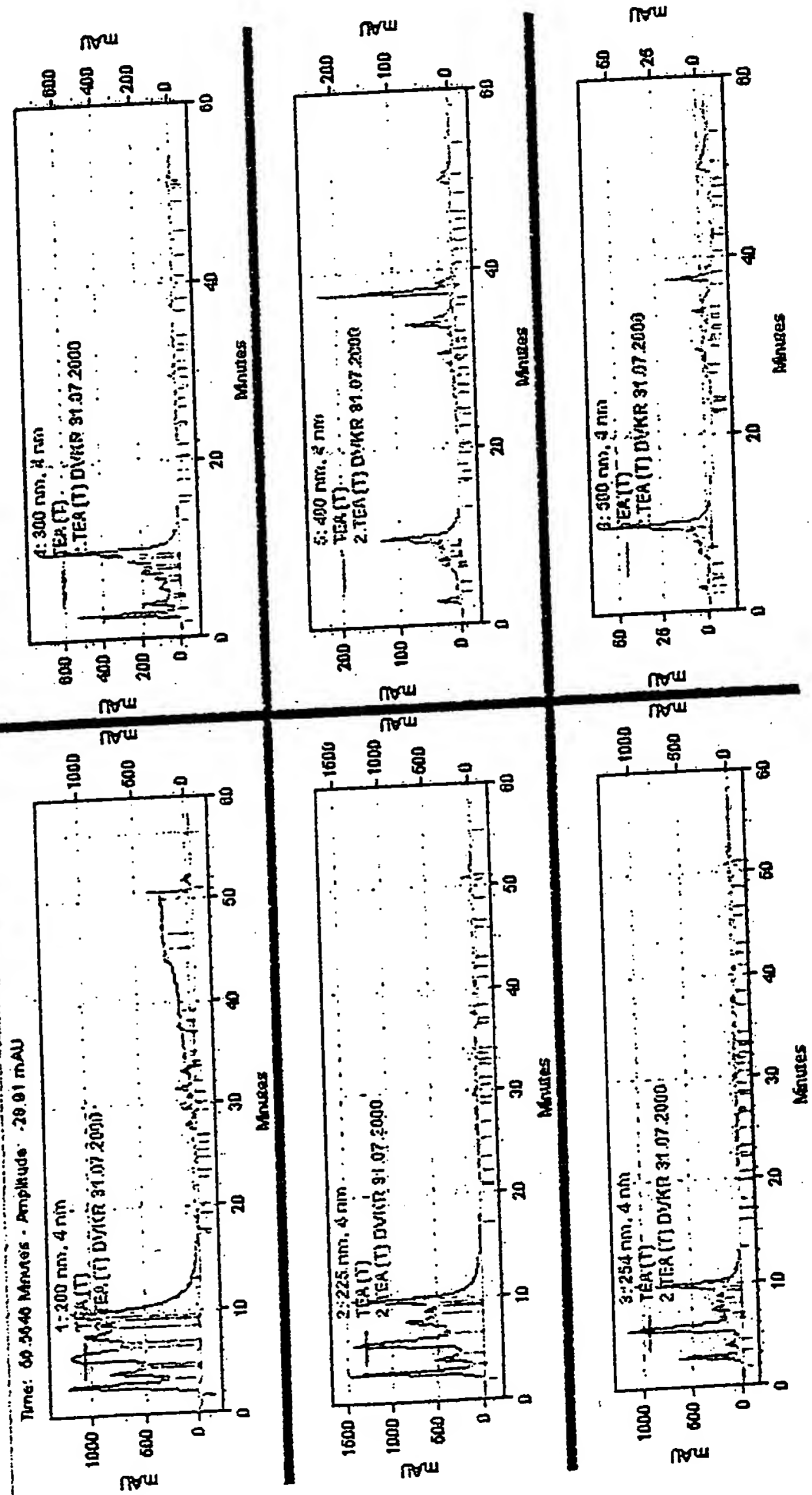


Figure 11

~~CHROMATOGRAMS OF A HERBAL FORMULATION~~  
~~TRIKTU (A FORMULATION OF PIPALI, MARICHA AND SHUNTI)~~  
~~AT DIFFERENT WAVELENGTHS~~  
~~(The existing method)~~

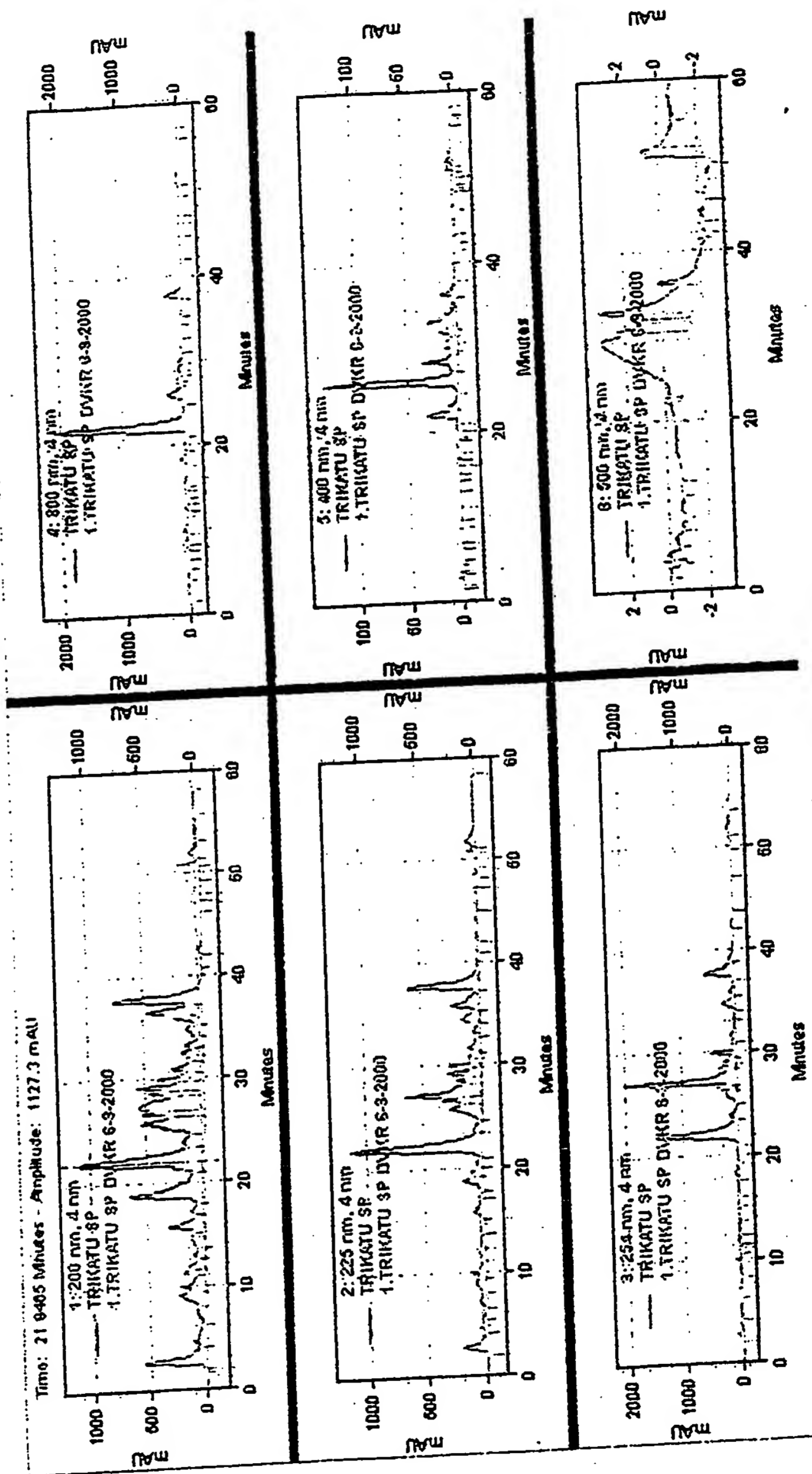
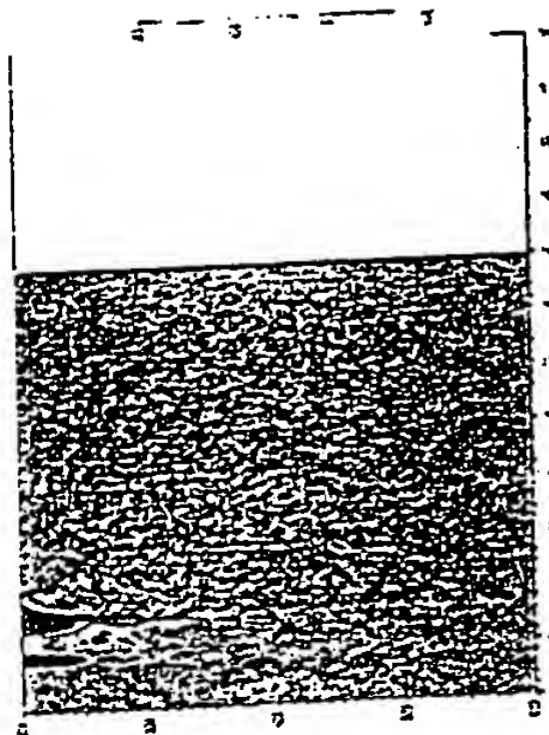


Figure 12

# ANNOTATED MARKED-UP DRAWINGS

## ~~THE YELLOW MEDICINES~~



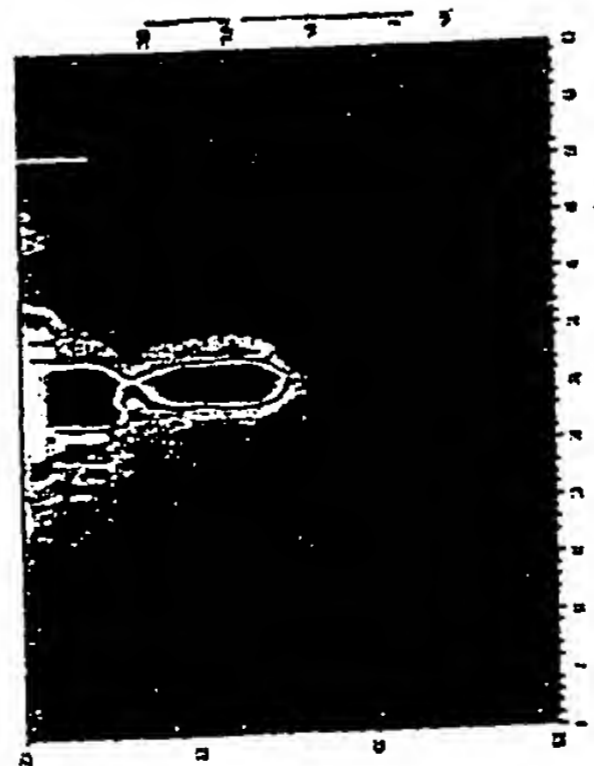
COSCINIUM  
FENESTRATUM



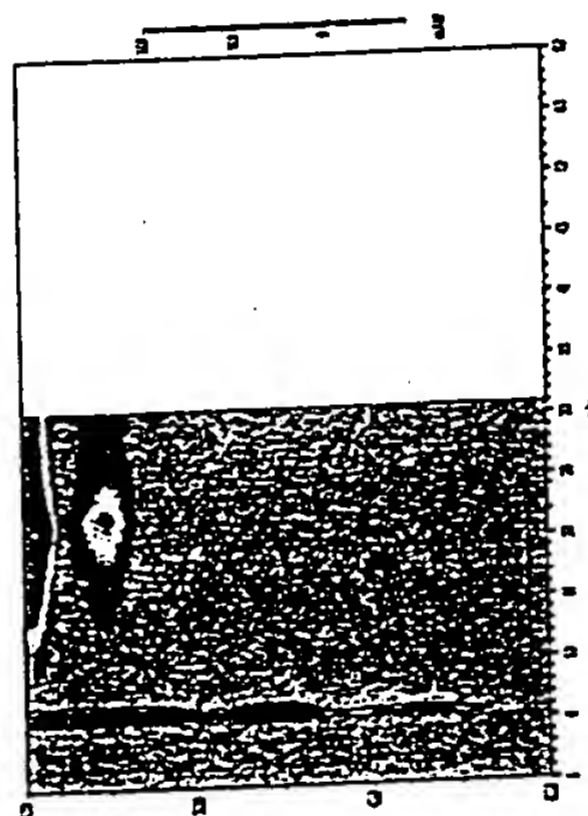
ZINZIBER OFFICINALE  
(PROCESSED)



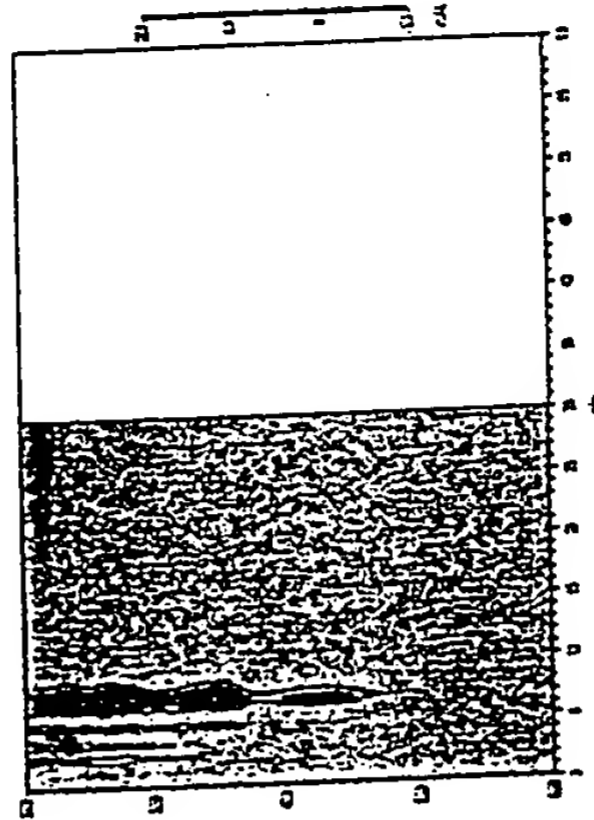
CURCUMA LONGA



CUMMIPHORA MUKUL



BERBERIN  
(FLUKA STANDARD)



BERBERIS ARISTATA

~~THE FINGERPRINTS OF CONTRAVERSIAL DRUGS (SANDIGDHA DRAYVAS) SHOWS  
A CLEAR DIFFERENCE IN APPEARANCE MAKING THE IDENTIFICATION MORE EASY.~~

Figure 13

# ANNOTATED MARKED-UP DRAWINGS

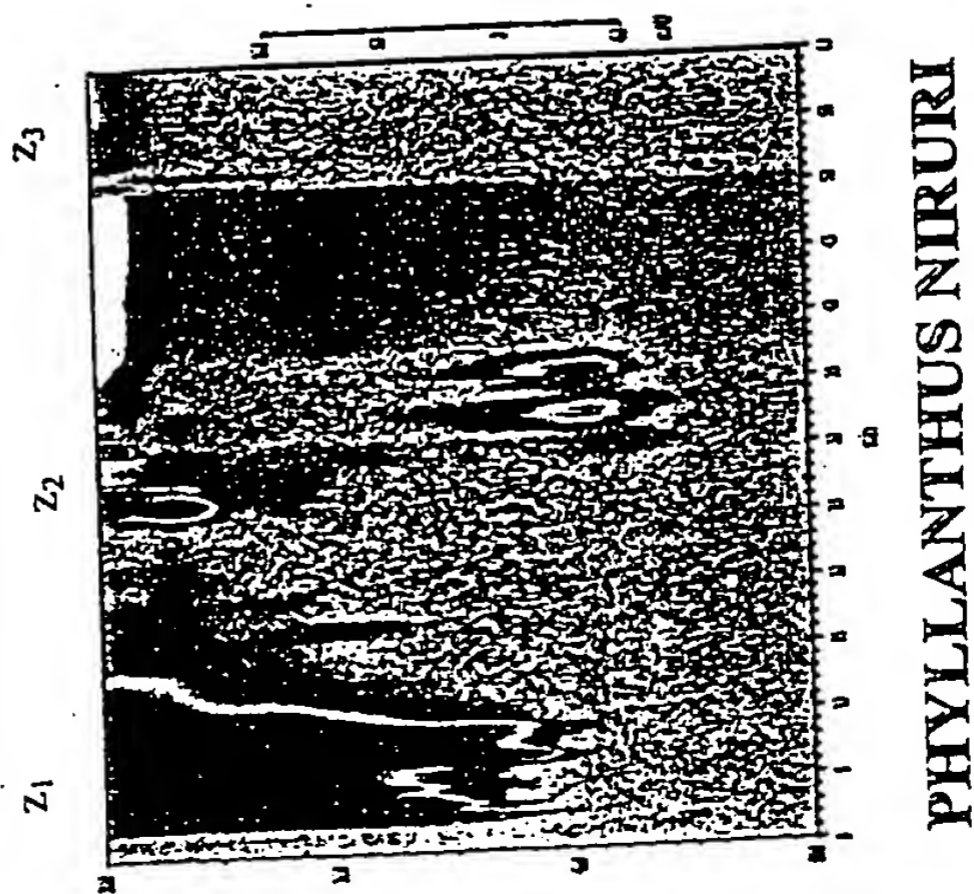
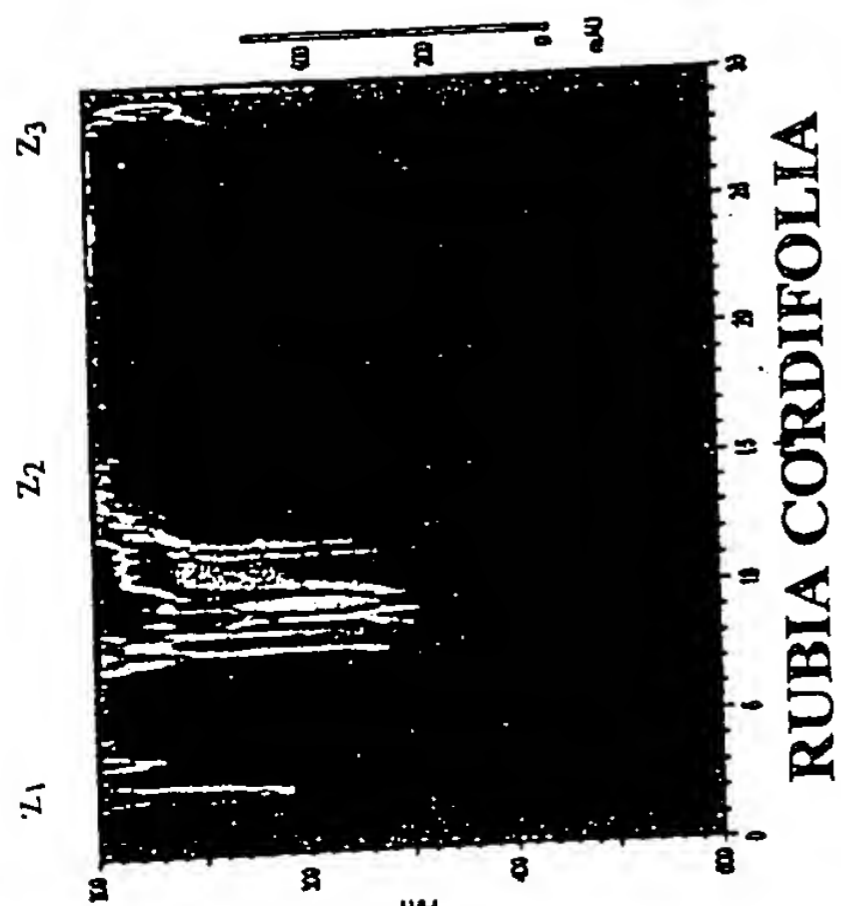
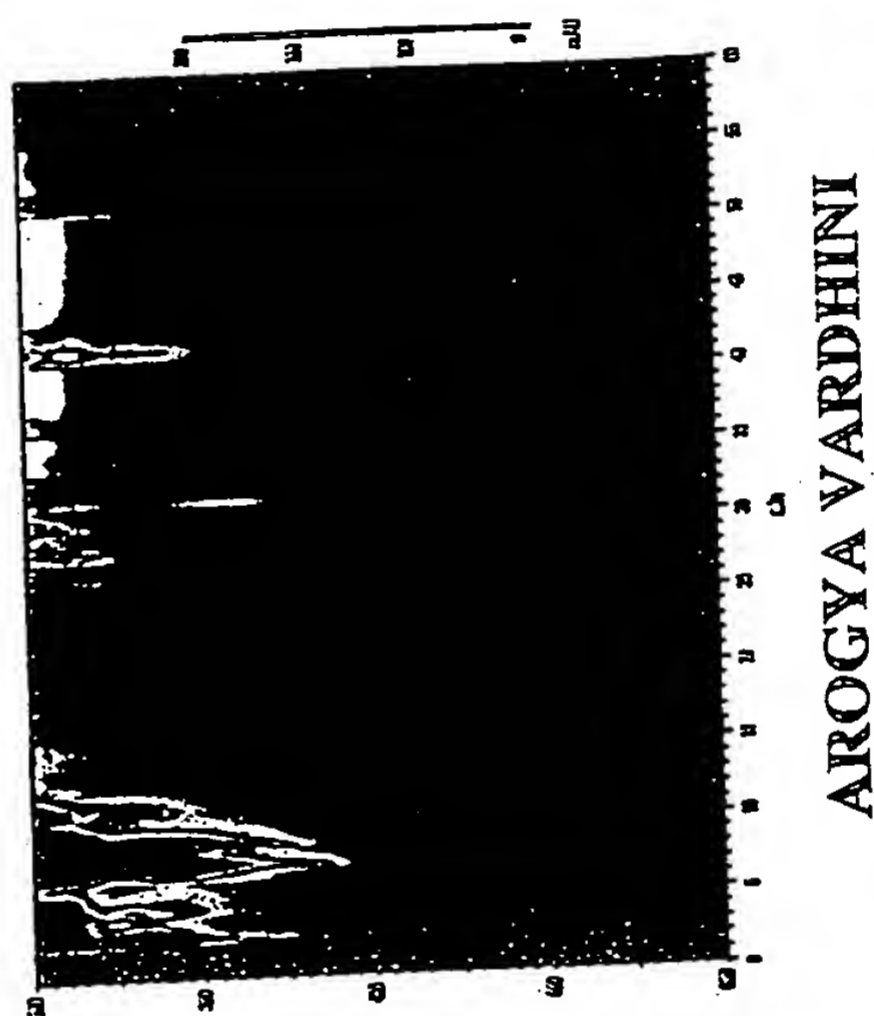
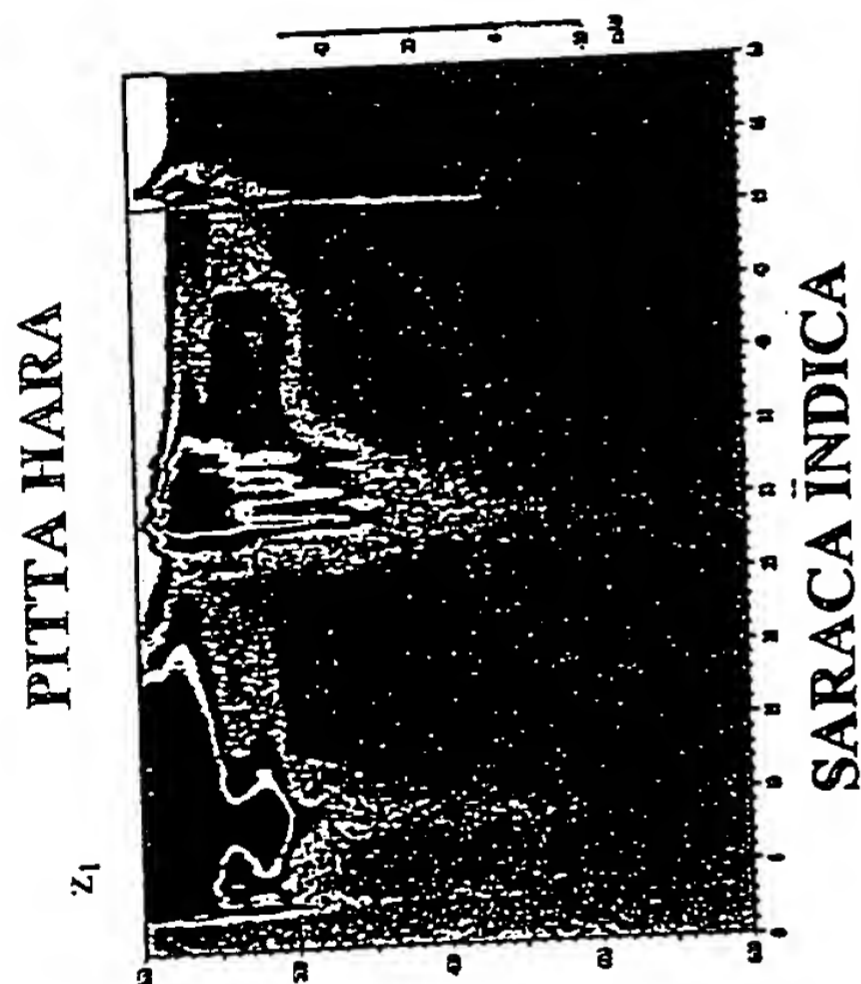
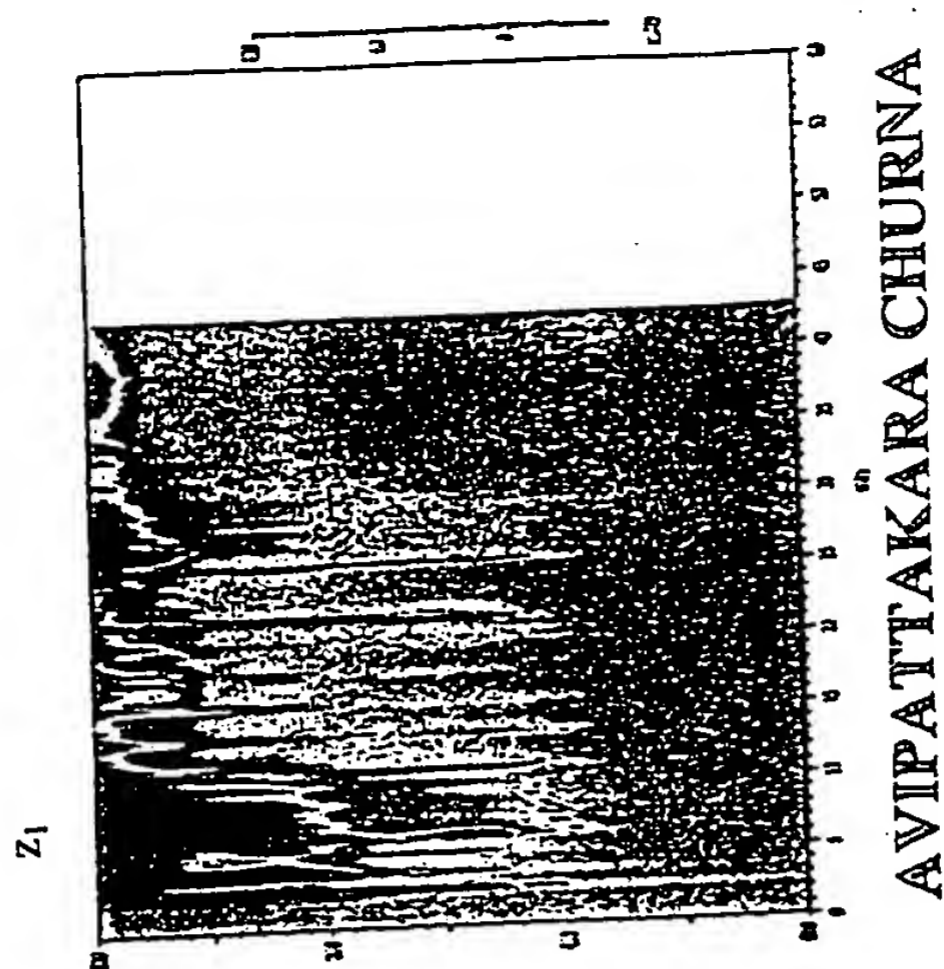
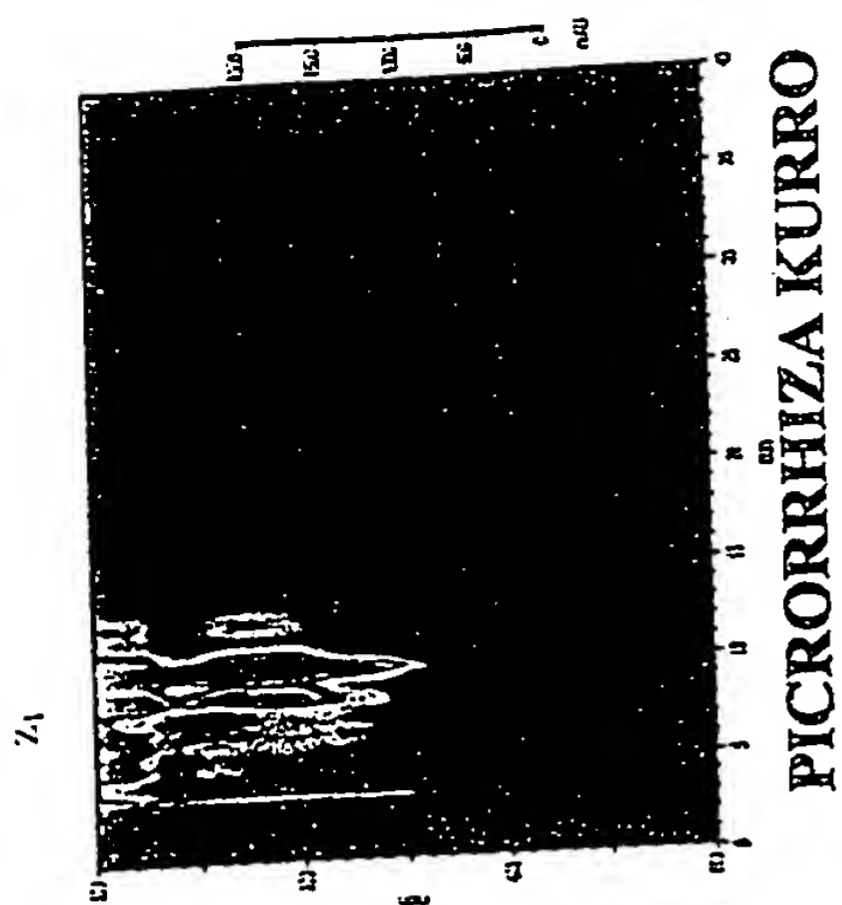
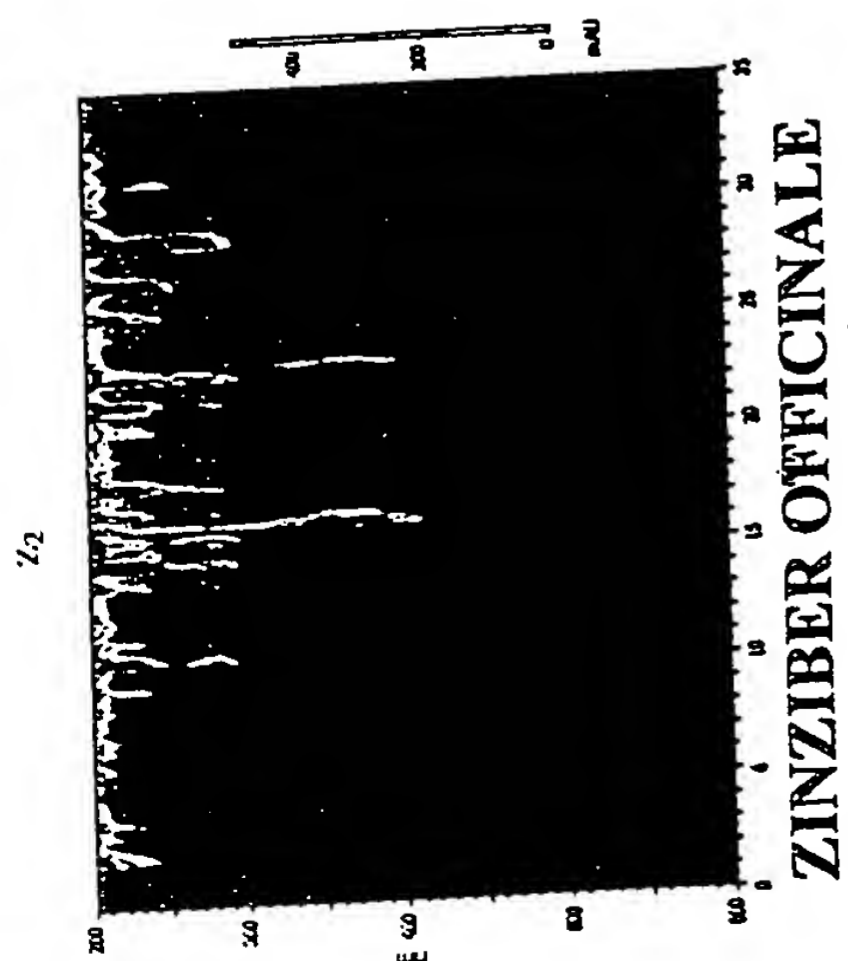
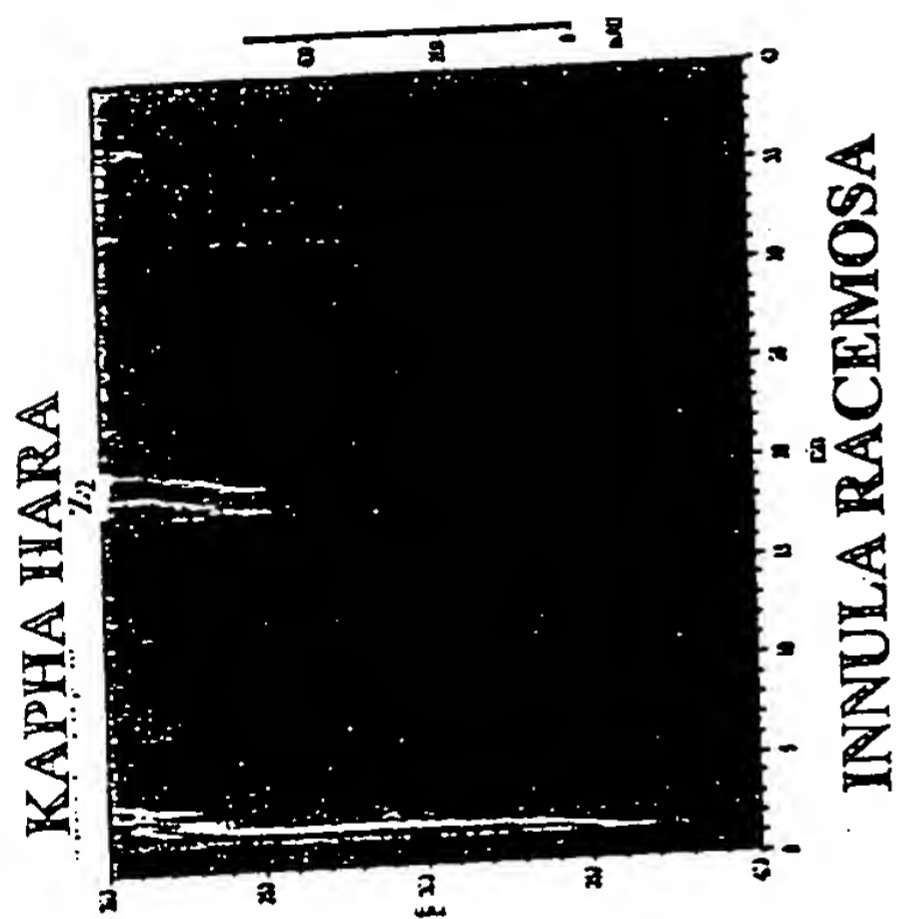
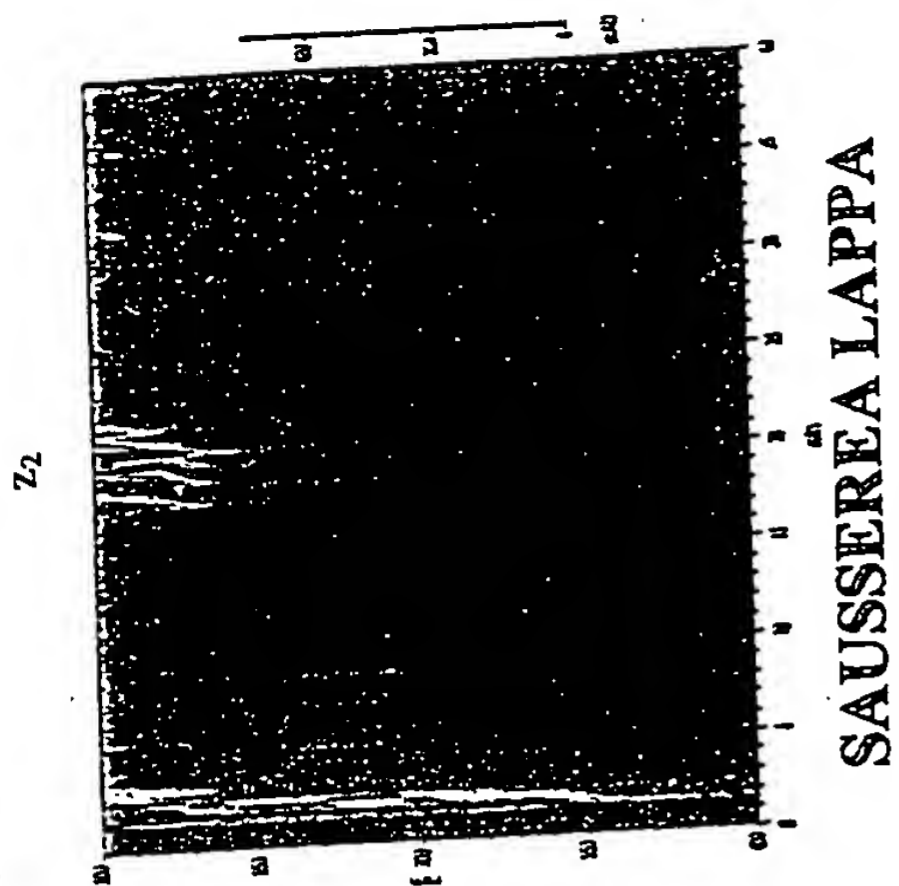


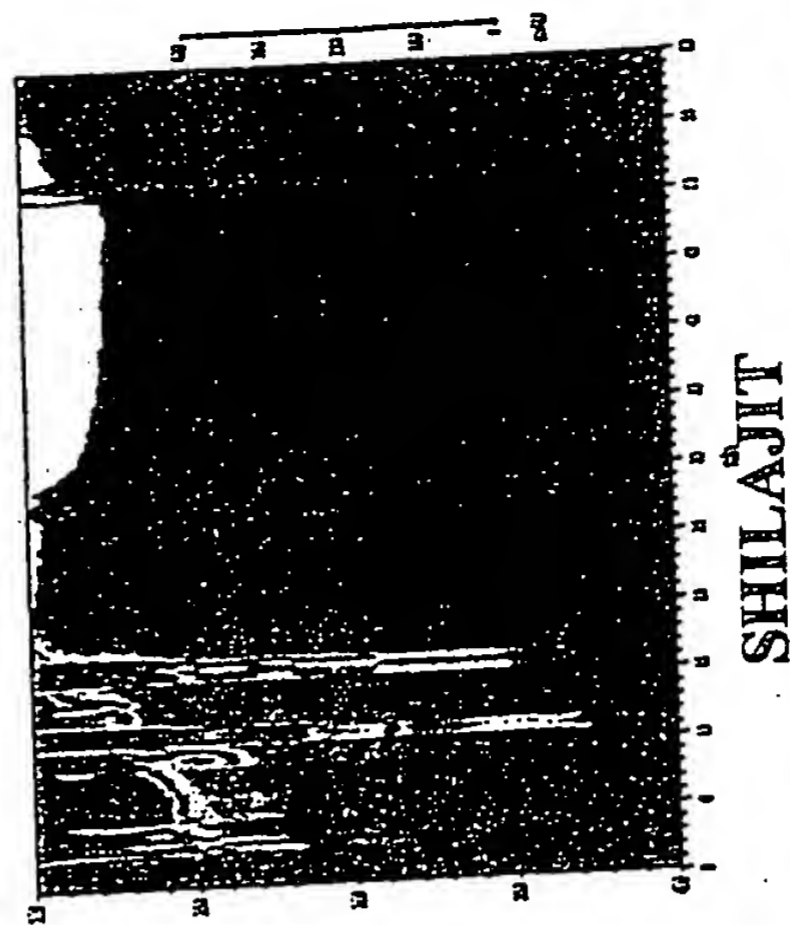
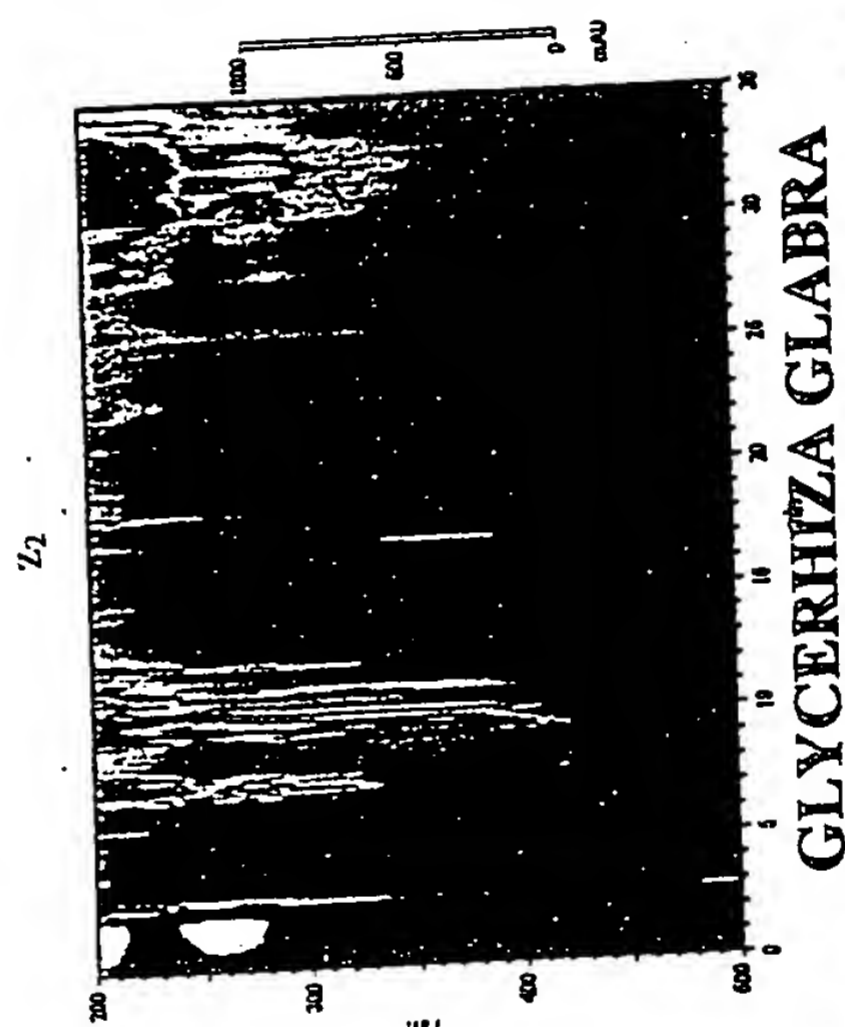
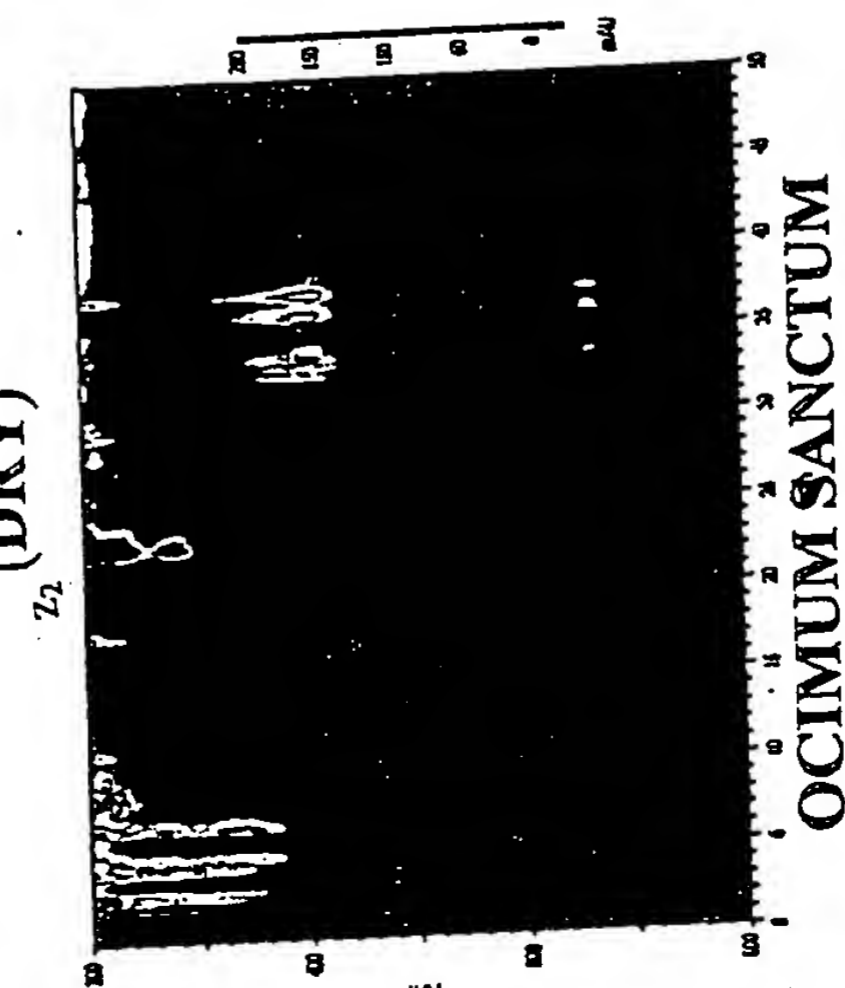
Figure 14

THE PRESENCE OF CONSTITUENTS IN ZONE I INDICATES THE SAID EFFICACY OF THE MEDICINES

# ANNOTATED MARKED-UP DRAWINGS



(DRY)



~~THE PRESENCE OF CONSTITUENTS IN ZONE 2 INDICATES THE SAID EFFICACY OF THE MEDICINES~~

Figure 15

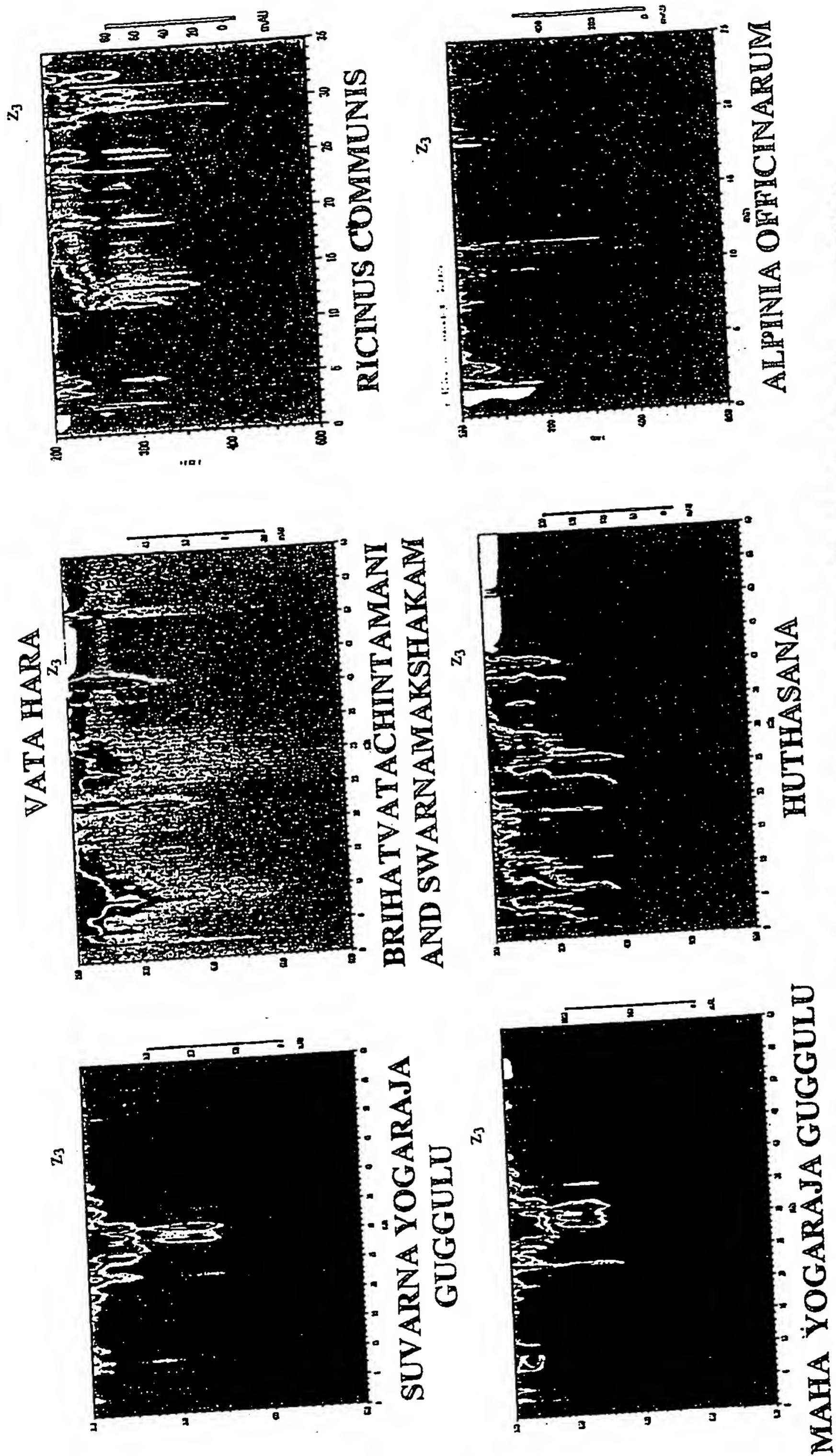
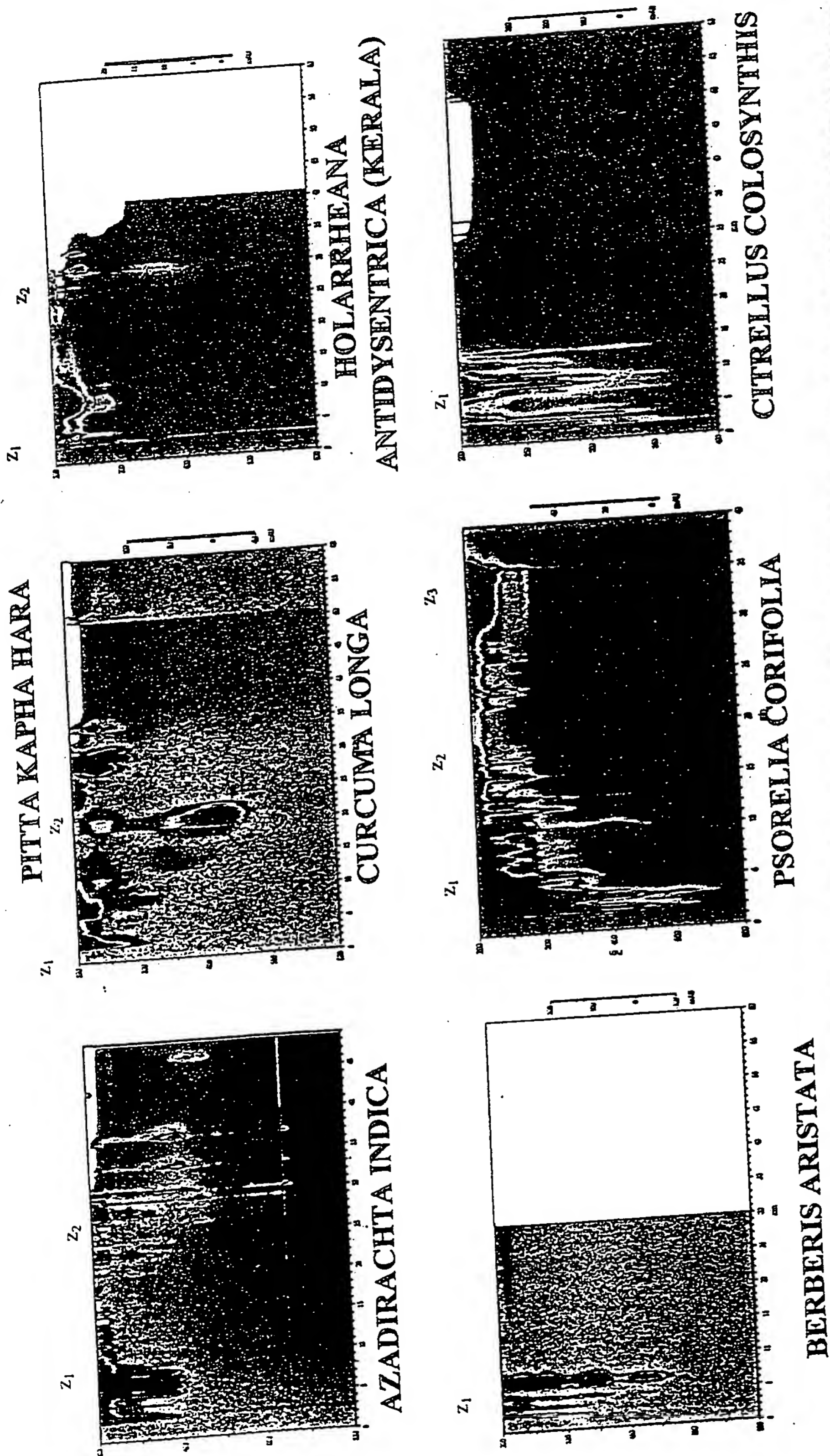


Figure 16

~~THE PRESENCE OF CONSTITUENTS ZONE 3 INDICATES THE SAID EFFICACY OF THE MEDICINES~~

# ANNOTATED MARKED-UP DRAWINGS



THE PRESENCE OF CONSTITUENTS IN ZONE 1 AND ZONE 2 INDICATES THE SAID EFFICACY OF THE MEDICINES

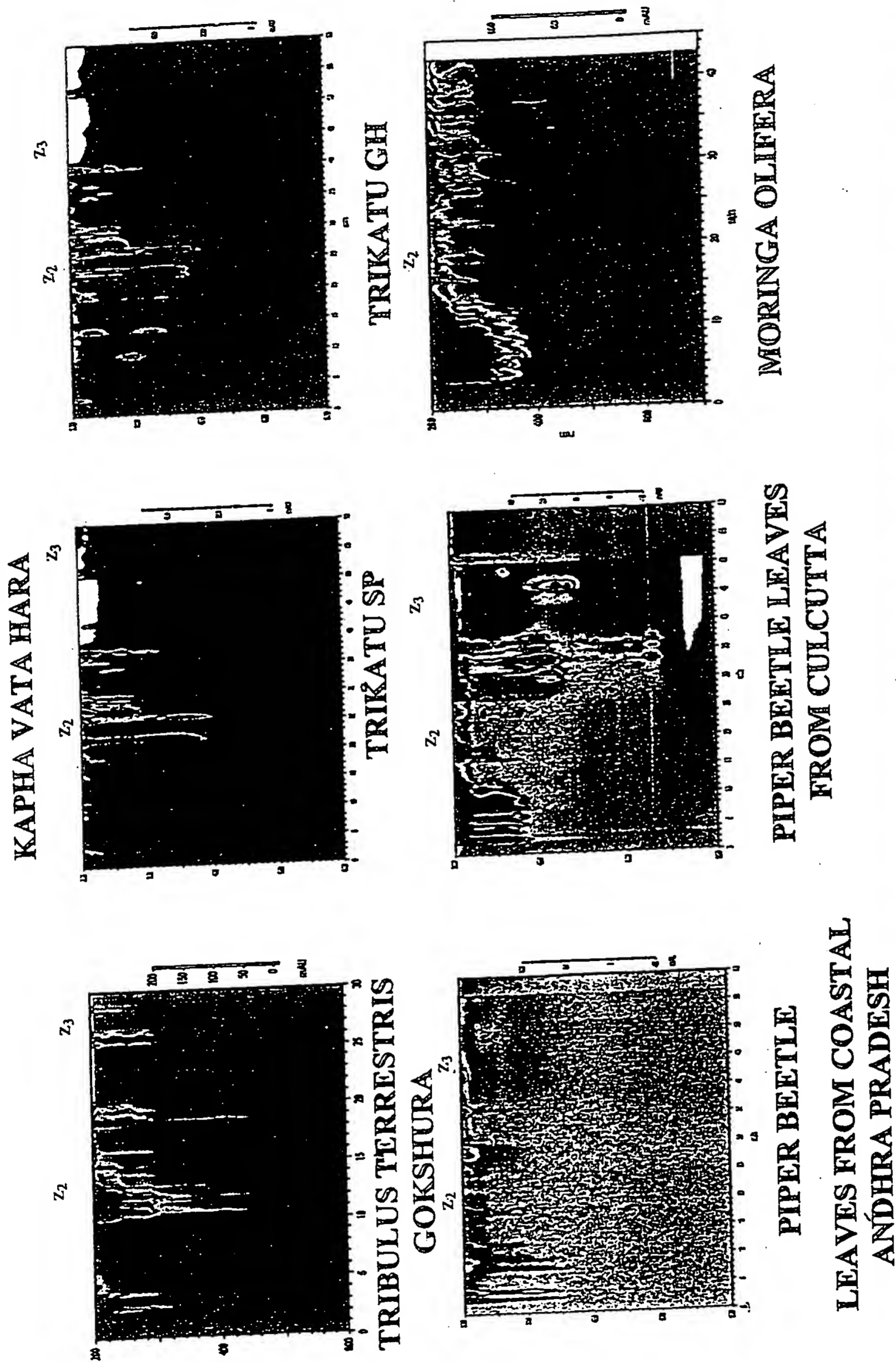


Figure 18

THE PRESENCE OF CONSTITUENTS IN ZONE 2 AND ZONE 3 INDICATES THE CAID EFFICACY OF THE MEDICINES

# ANNOTATED MARKED-UP DRAWINGS

## PITTA VATA HARA

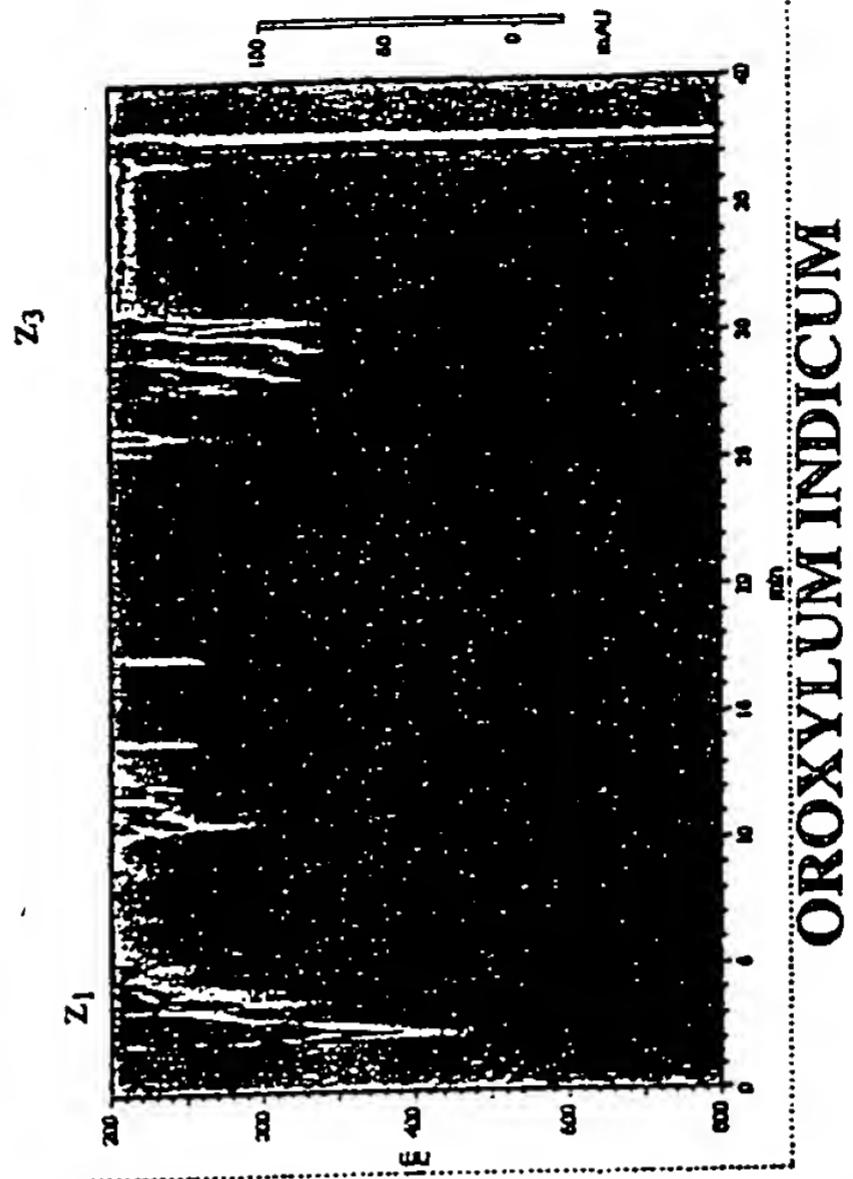
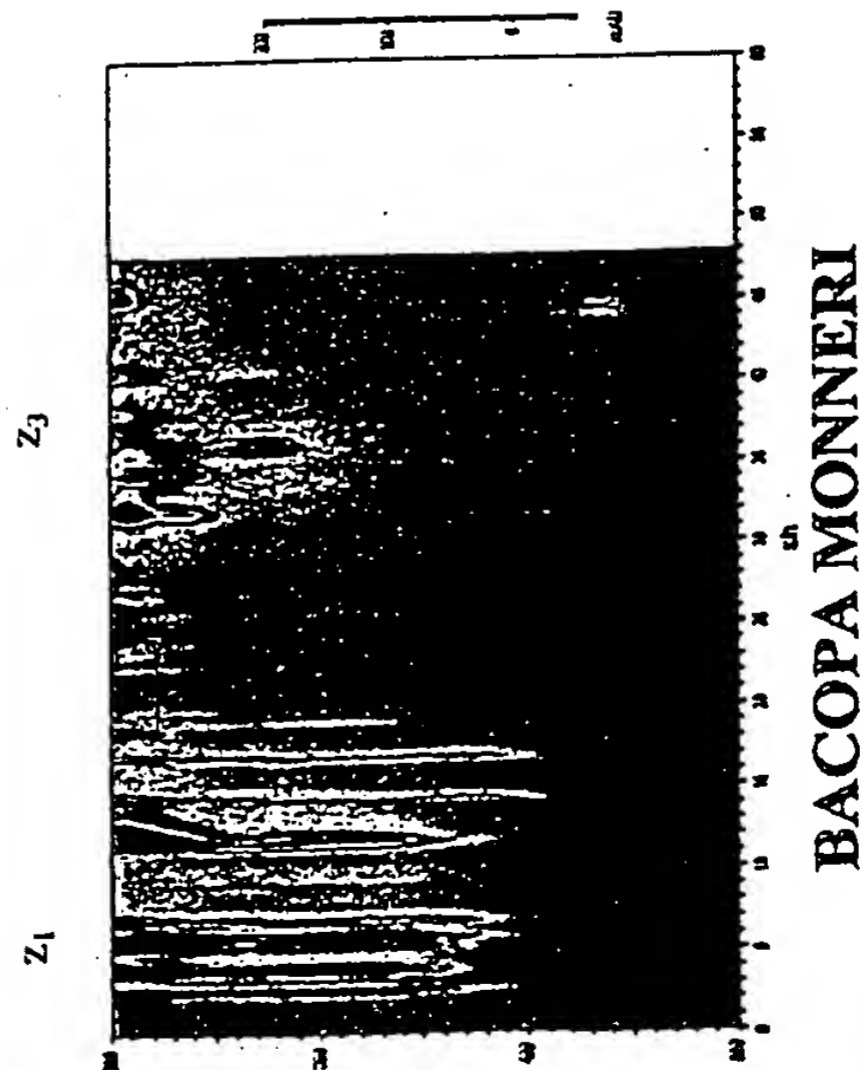
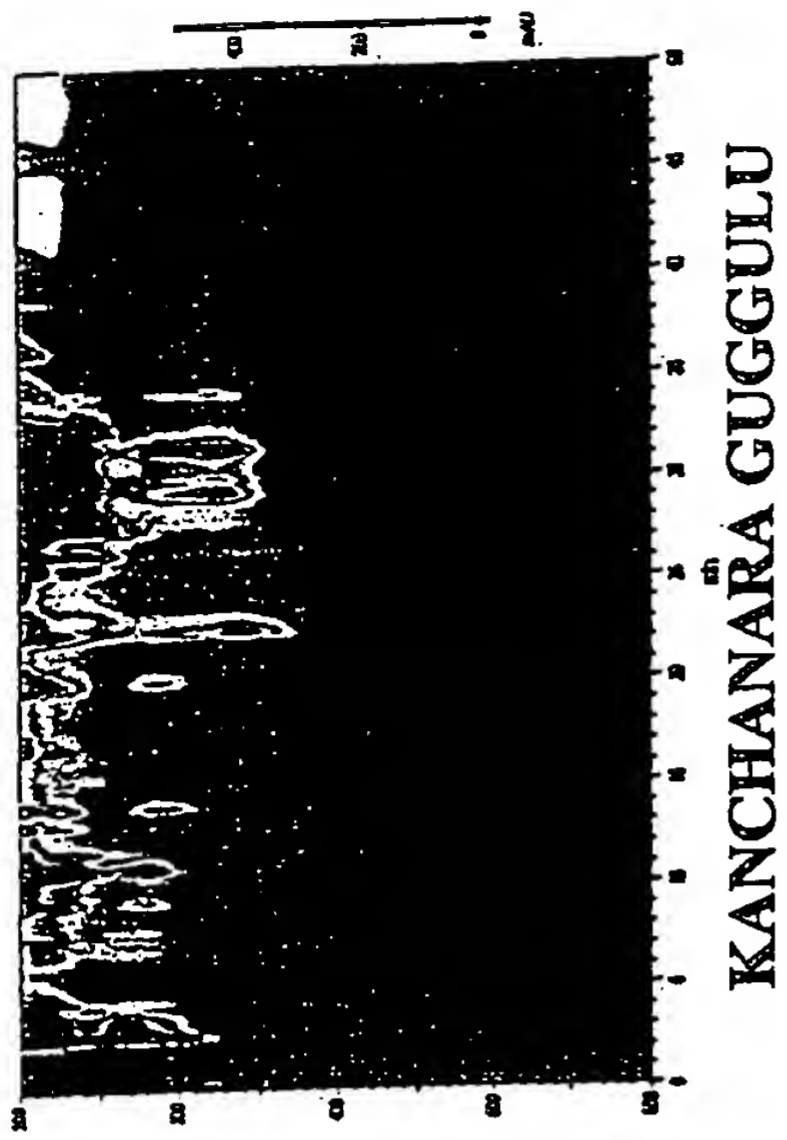
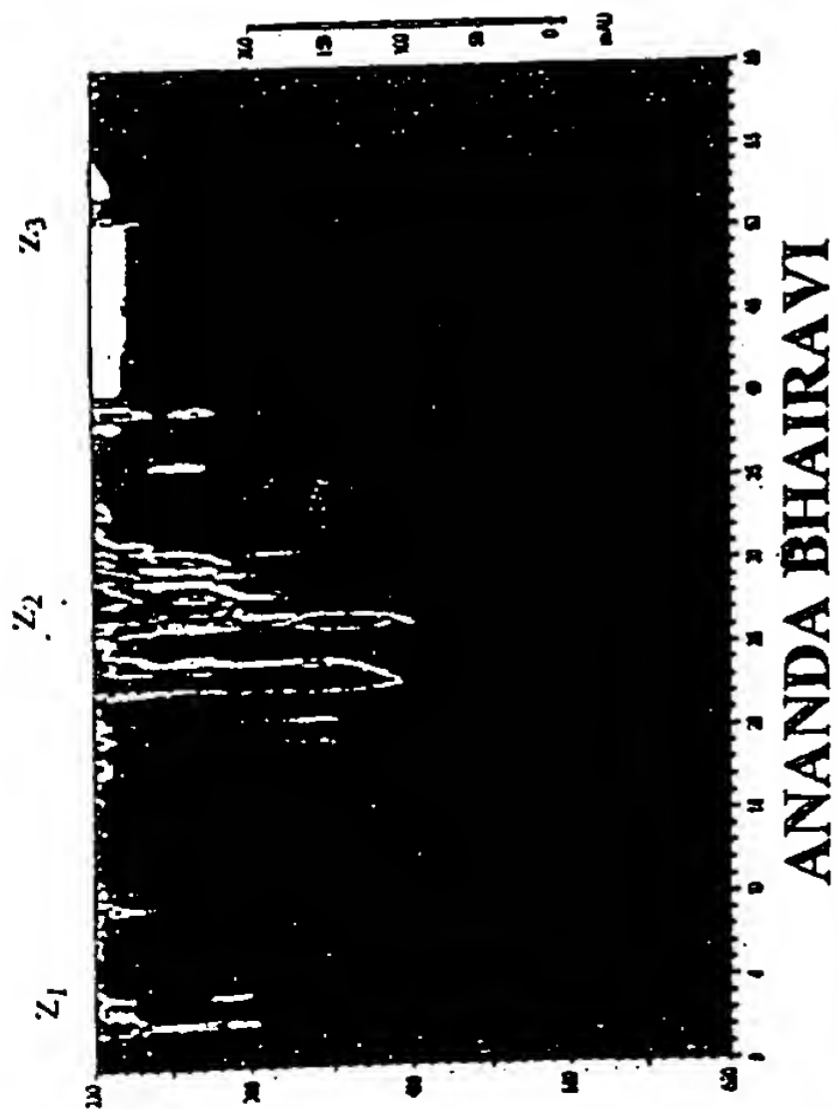
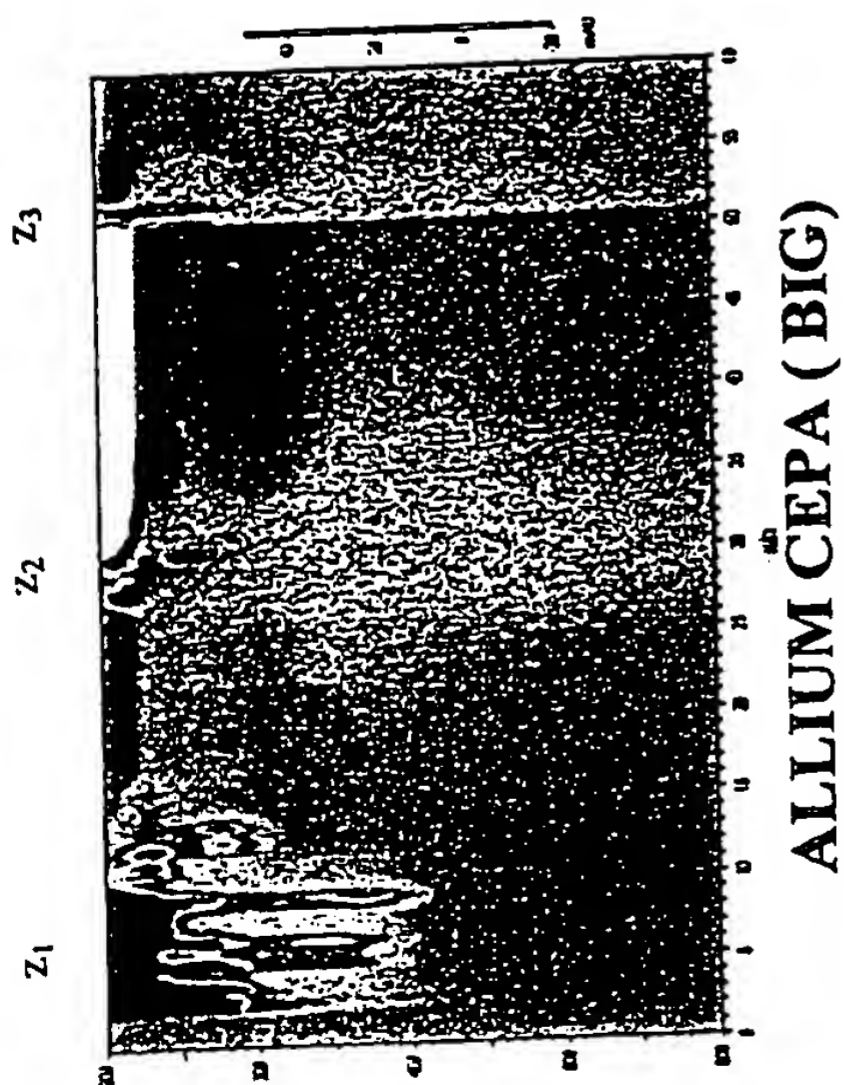


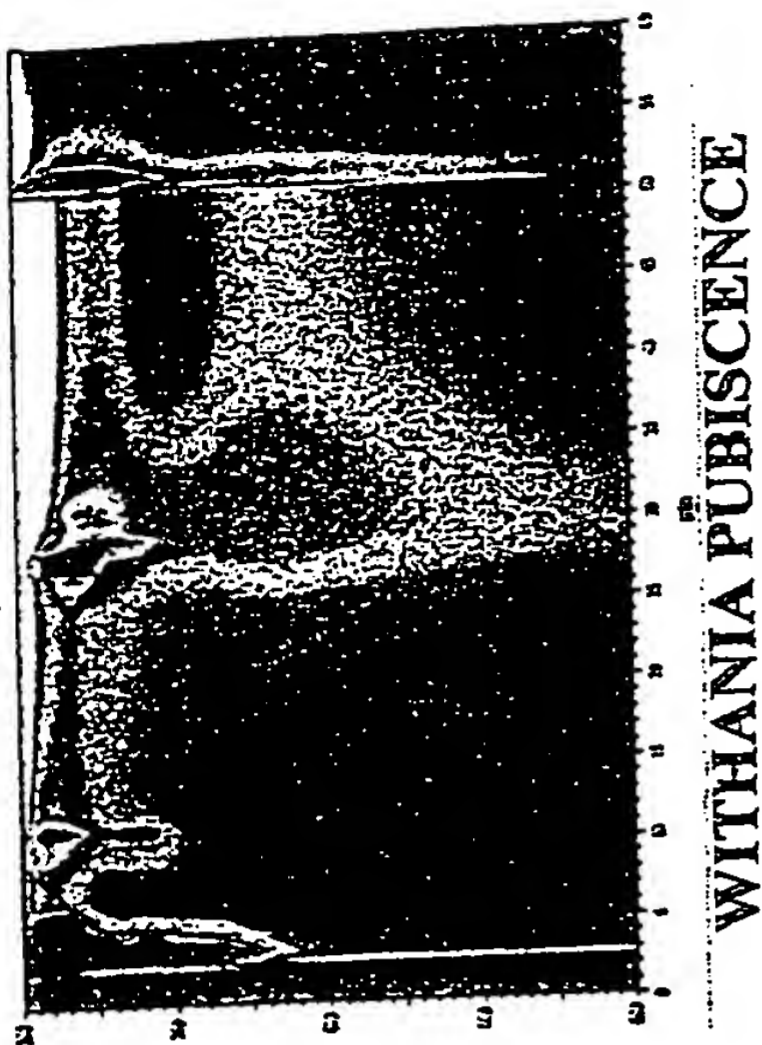
Figure 19

THE PRESENCE OF CONSTITUENTS IN ZONE-1 AND ZONE-3 INDICATES THE SAID EFFICACY OF THE MEDICINES

TRI DOSHA HARA

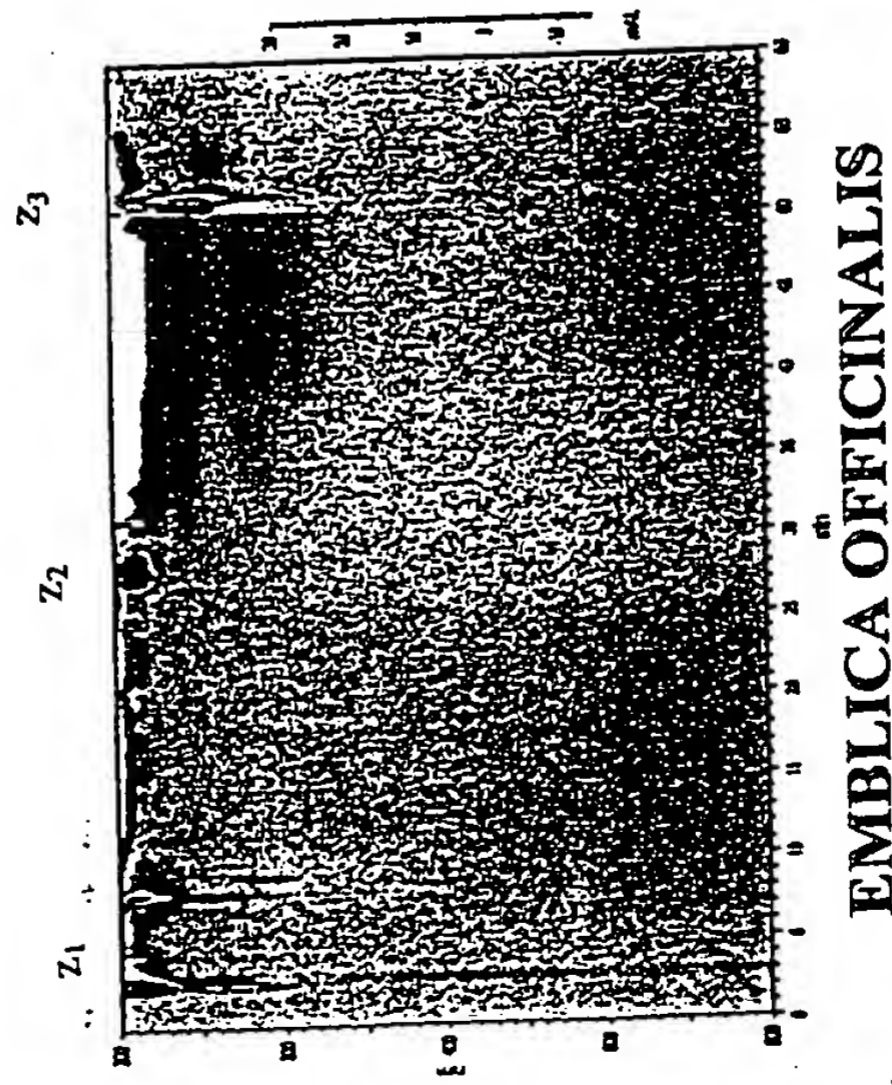


ALLIUM CEPA (BIG)

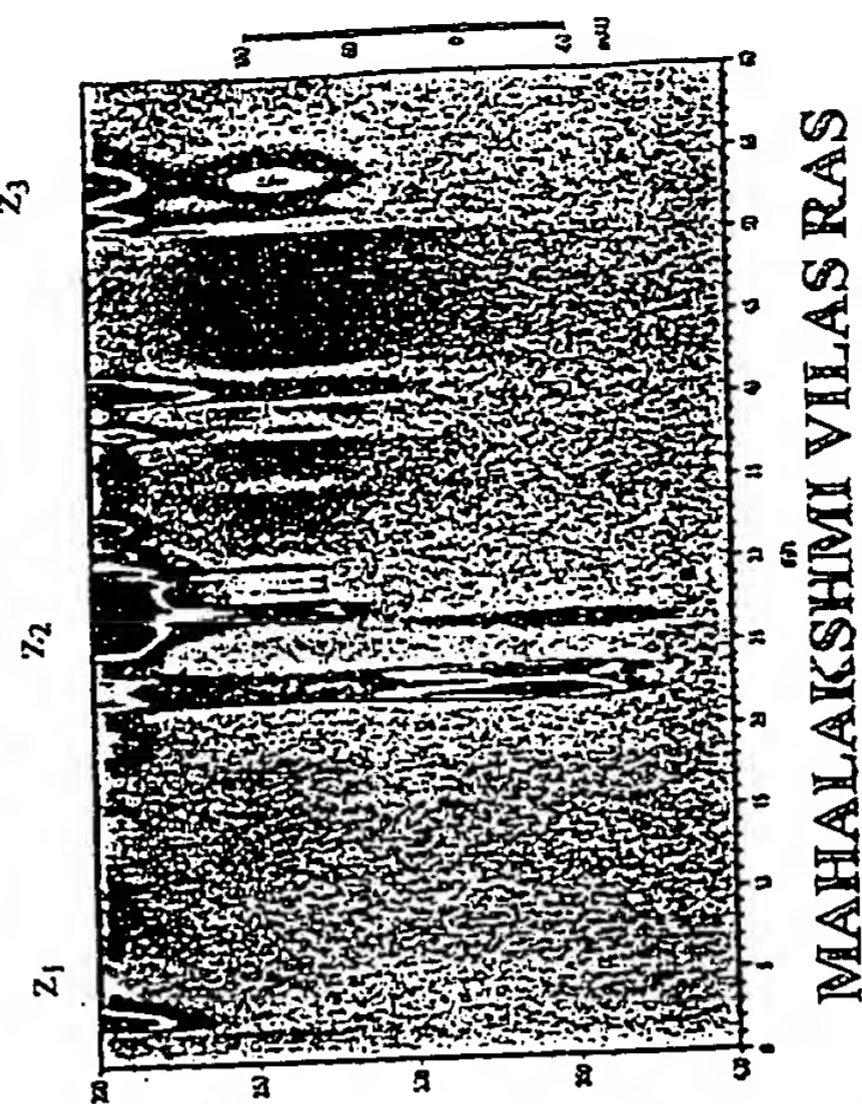


WITHANIA PUBESCENCE

RED SEEDS



EMBLICA OFFICINALIS

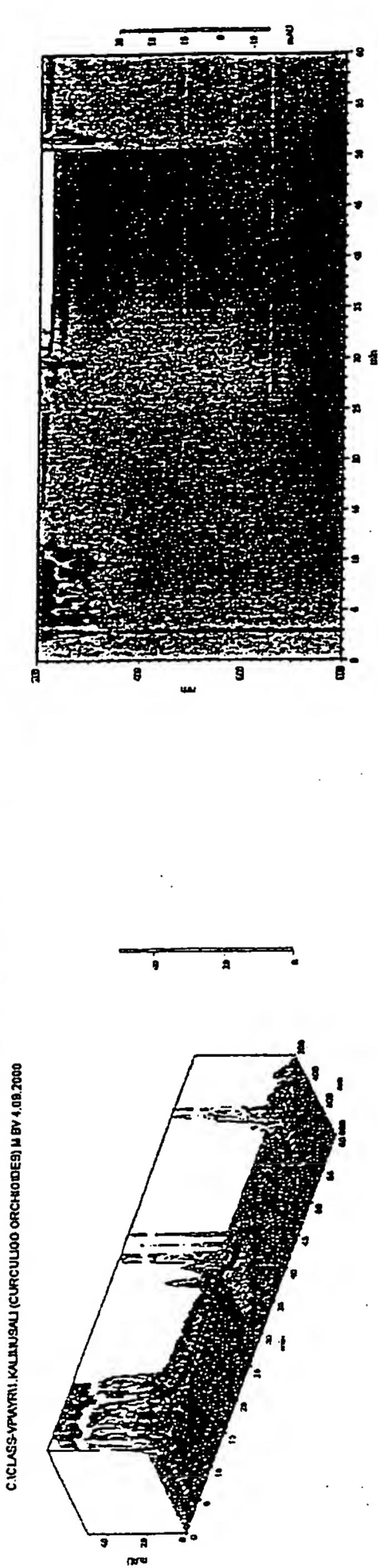


MAHALAKSHMI VILAS RAS

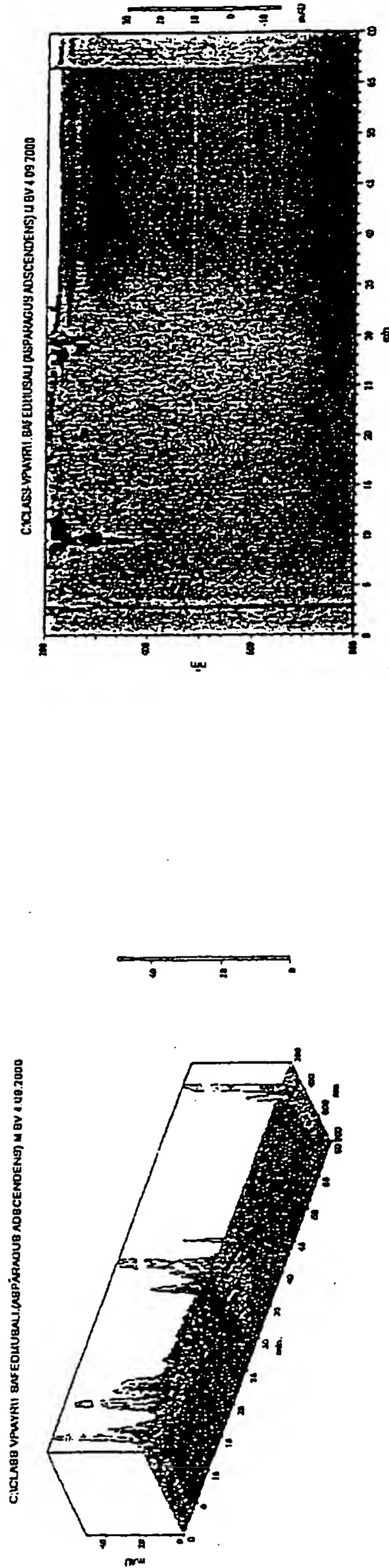
~~THE PRESENCE OF CONSTITUENTS IN ALL THREE ZONES INDICATES THE SAID EFFICACY OF THE~~  
~~MEDICINE~~

Figure 20

Figure: ~~MUSALI - A TRIDOSHHA HARA MEDICINE~~



FINGER PRINTS OF CURCULIGO ORCHOIDIS (KALIMUSALI)



FINGER PRINT OF ASPARAGUS ADESCENDENS (SAFED MUSALI)

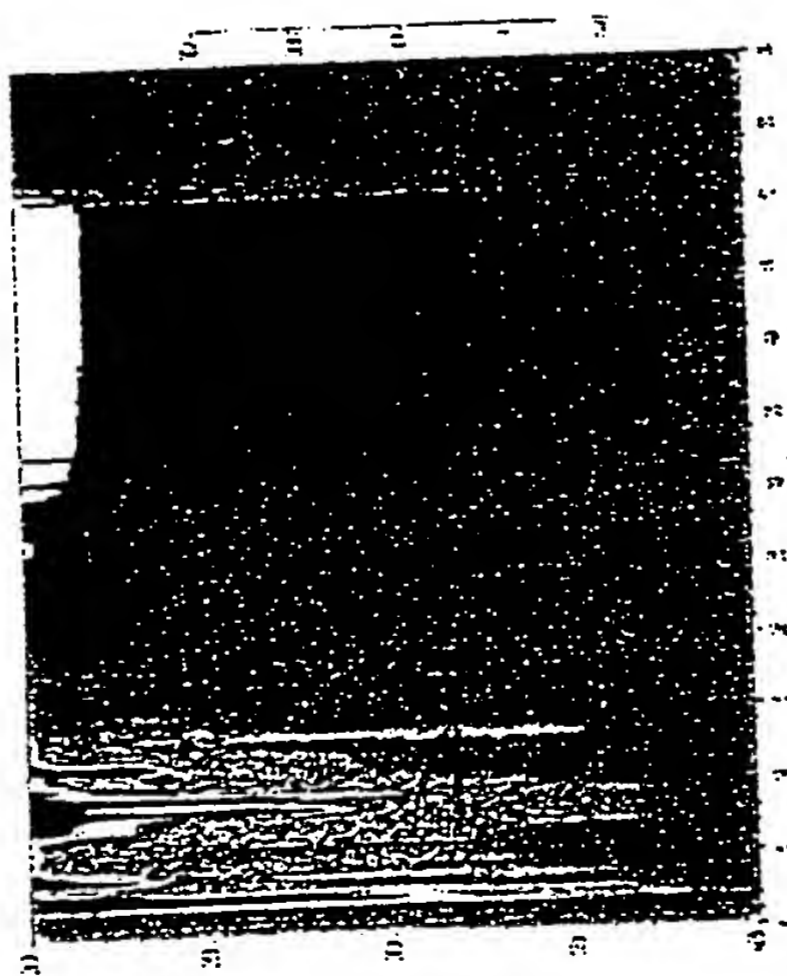
Figure 21

~~CITRULLUS COLOSYNTHIS~~

~~(HOMEO MEDICINE)~~

~~Light in bitterness absent~~

~~Very bitter peak of difference~~



~~CITRULLUS COLOSYNTHIS~~

~~GOOD BY EFFICACY~~



~~CITRULLUS COLOSYNTHIS~~

~~POOR BY EFFICACY~~

~~THE LACK OF SOME CONSTITUENTS IN THE FINGER PRINT SHOWS THE USE OF THIS METHOD FOR THE  
STANDARDIZATION OF EXTRACTION PROCESS OF HOMEO-MOTHER TINCTURES FROM PLANTS  
THIS supports the claim of taste identification used for therapeutic standardization.~~

Figure 22

~~INFLUENCE OF ECOLOGICAL FACTORS~~

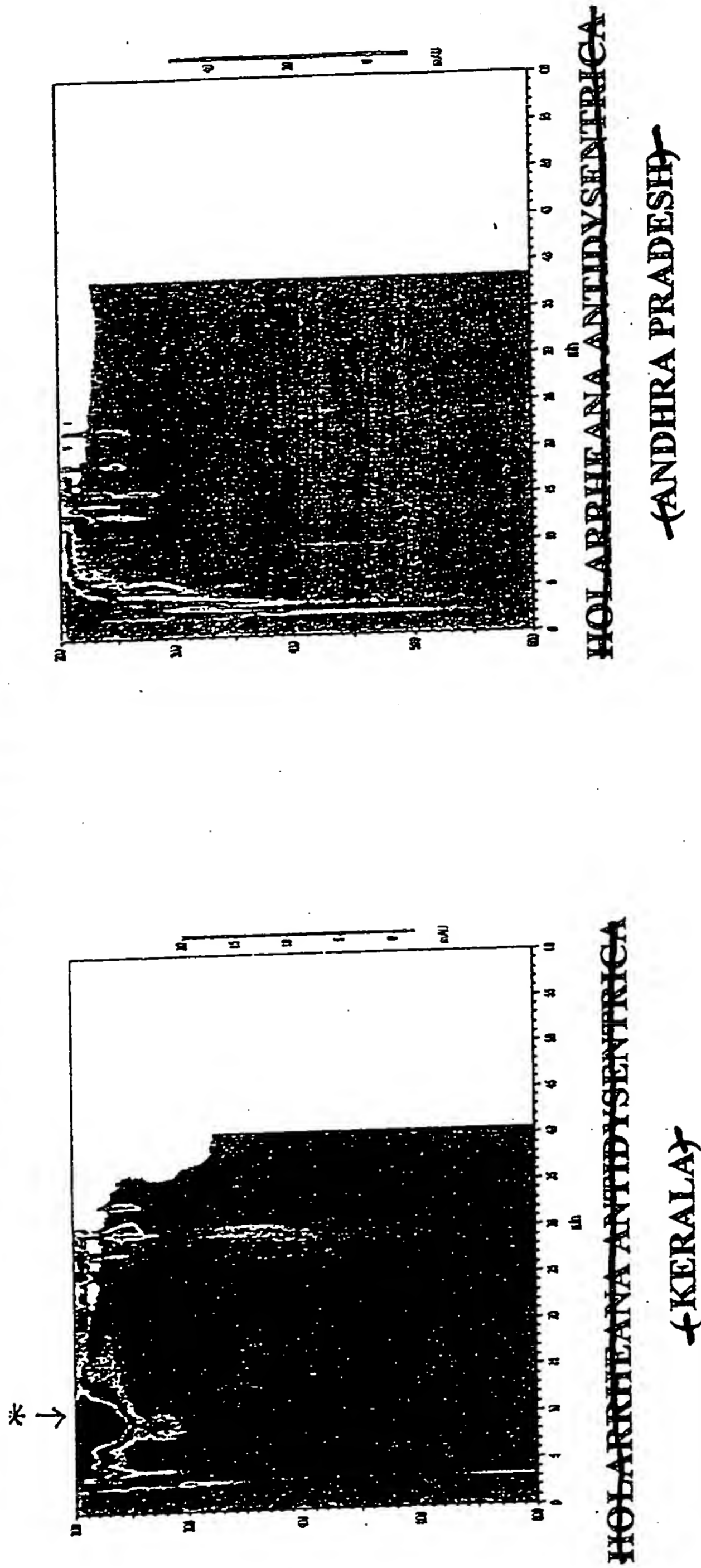


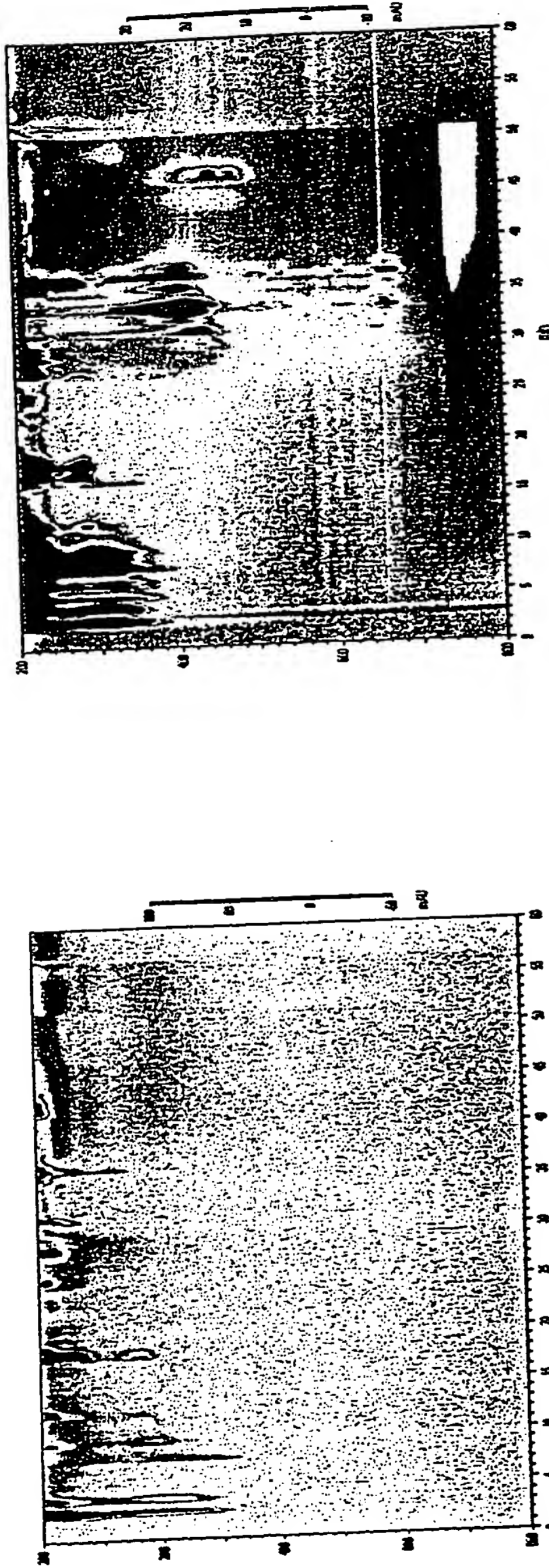
Figure 23

~~THE FINGER-PRINTS SHOWS THE INFLUENCE OF ECOLOGICAL FACTORS ON THE~~  
~~CHEMICAL CONSTITUENTS OF THE PLANT MATERIAL OF~~  
~~DIFFERENT TROPICAL ZONES OF THE COUNTRY.~~

\* ~~This constituent is basic in nature because the basic or alkaline amines elutes stretched~~  
~~or elongated. Acid compounds elute fast like a sharp peak.~~

Figure 24

~~PIPER BEETLE EXAMPLE~~



BEETLE LEAVES FROM  
CALCUTTA

BEETLE LEAVES FROM COASTAL  
ANDHRA PRADESH

~~Aurones and Chalcones (flavonoids) are antioxidants. A combinatorial library of~~  
~~can be seen~~

~~THE FLAVONOIDS PRESENT IN THE TIME RANGE OF 30-40 MIN SHOWS THE INFLUENCE OF~~  
~~GENOTYPIC, PHENOTYPIC VARIATIONS AND ECOLOGICAL FACTORS ON THE CHEMICAL~~  
~~CONSTITUENTS OF THE PLANT MATERIAL OF DIFFERENT~~

~~TROPICAL ZONES OF THE COUNTRY~~

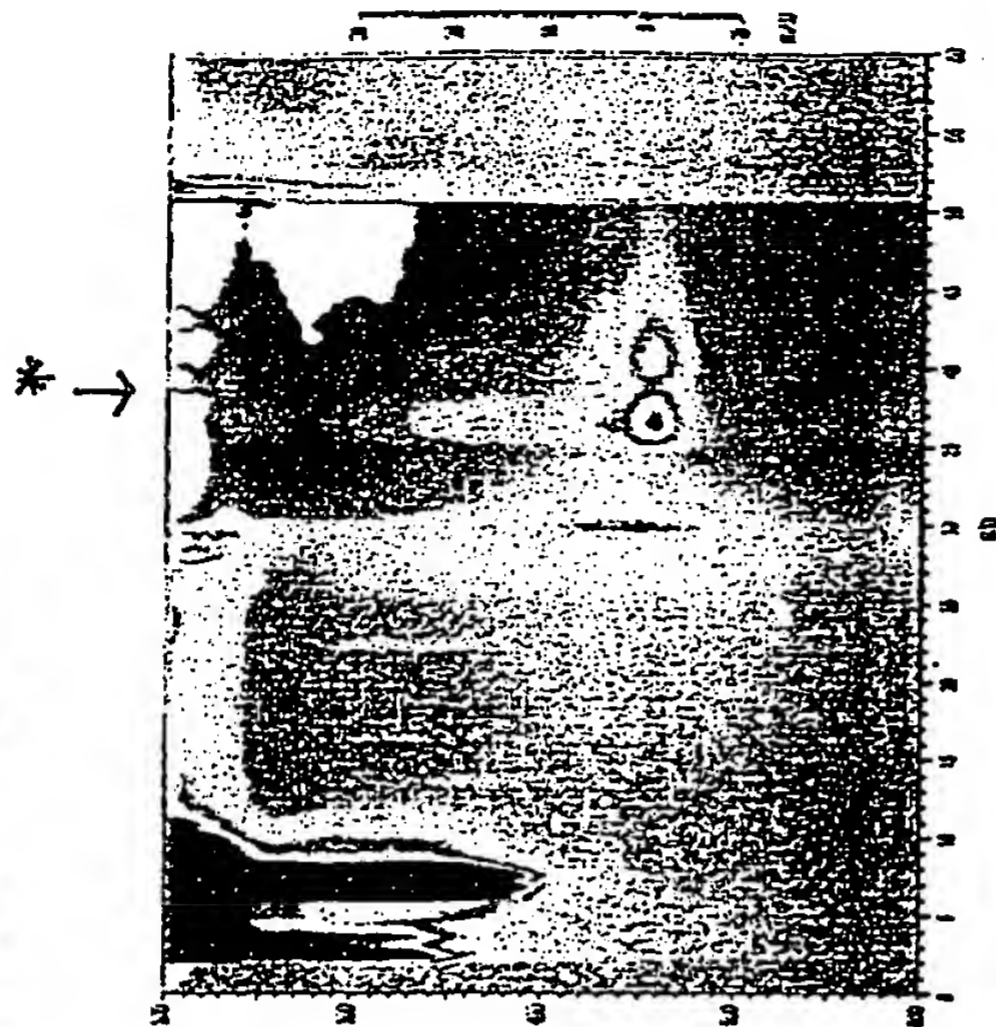
Figure 26

~~HERBAL HEAD BATH POWDERS~~



~~HERBAL HEAD BATH POWDER~~

PURE



~~HERBAL HEAD BATH POWDER~~

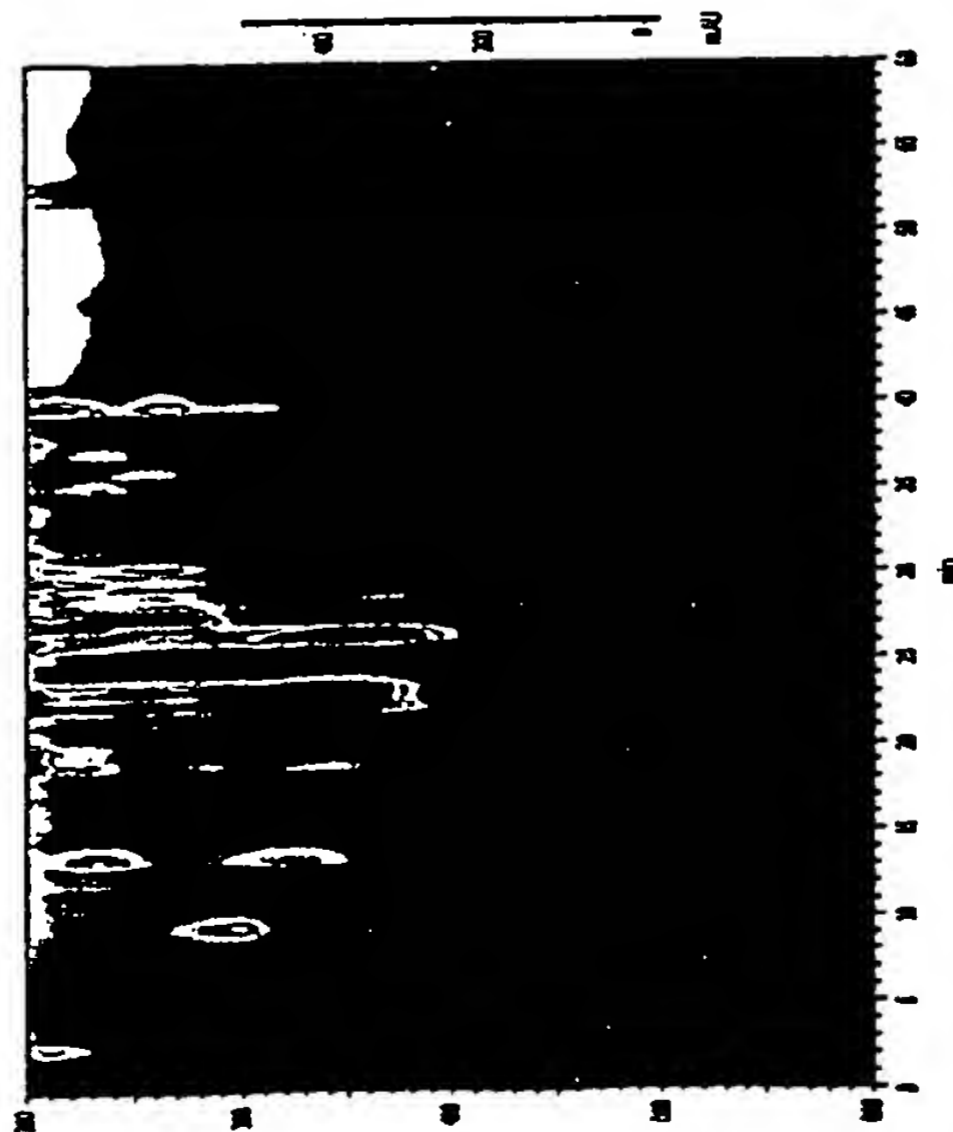
ADULTERATED

~~THE ABOVE FINGER PRINTS SHOW THE ADULTERATION OF DETERGENTS IN THE SAID  
HERBAL COSMETIC PRODUCT. THUS FINGER PRINTING HELPS TO MONITOR THE  
ADULTERATIONS IN VARIOUS COMMERCIAL HERBAL PRODUCTS~~

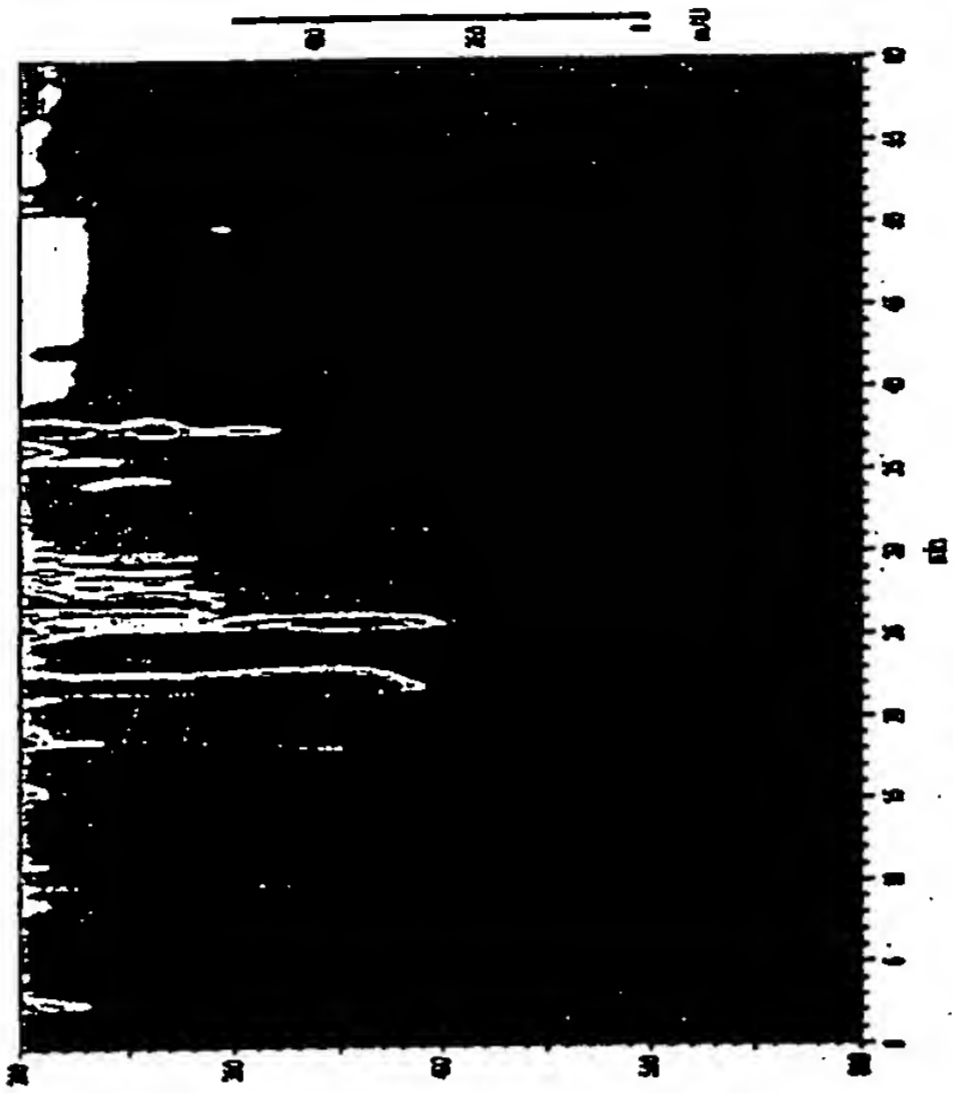
~~\* -> Constituents at 35-40 minutes are highly basic and soapy in nature. The pure detergent  
sample are eluting at the same time~~

Figure 27

~~HERBAL FORMULATIONS OF  
DIFFERENT BRANDS~~



TRIKATU - BRAND 1



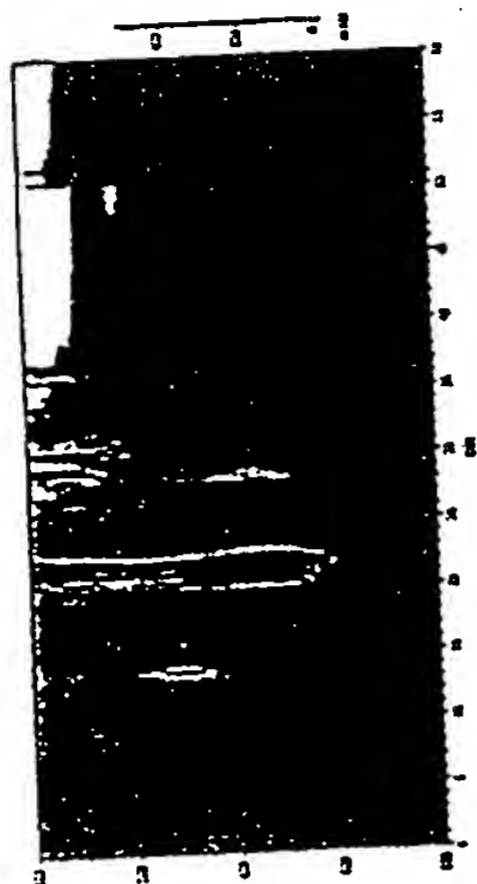
TRIKATU - BRAND 2

~~THE ABOVE EXAMPLE OF TRIKATU SHOWS DIFFERENCE IN THE ASSAY AND VARIATIONS  
IN THE CHEMICAL CONSTITUENTS. THE REASON MAY BE DUE TO THE VARIATIONS IN  
THE SINGLE MEDICINES USED TO PREPARE THE FORMULATIONS.~~

~~COMPARATIVE EXAMPLE~~



CURCUMA LONGA BRAND - 1



CURCUMA LONGA BRAND - 2



CURCUMA LONGA BRAND - 3



CURCUMA LONGA

(NATURAL RHIZOME)

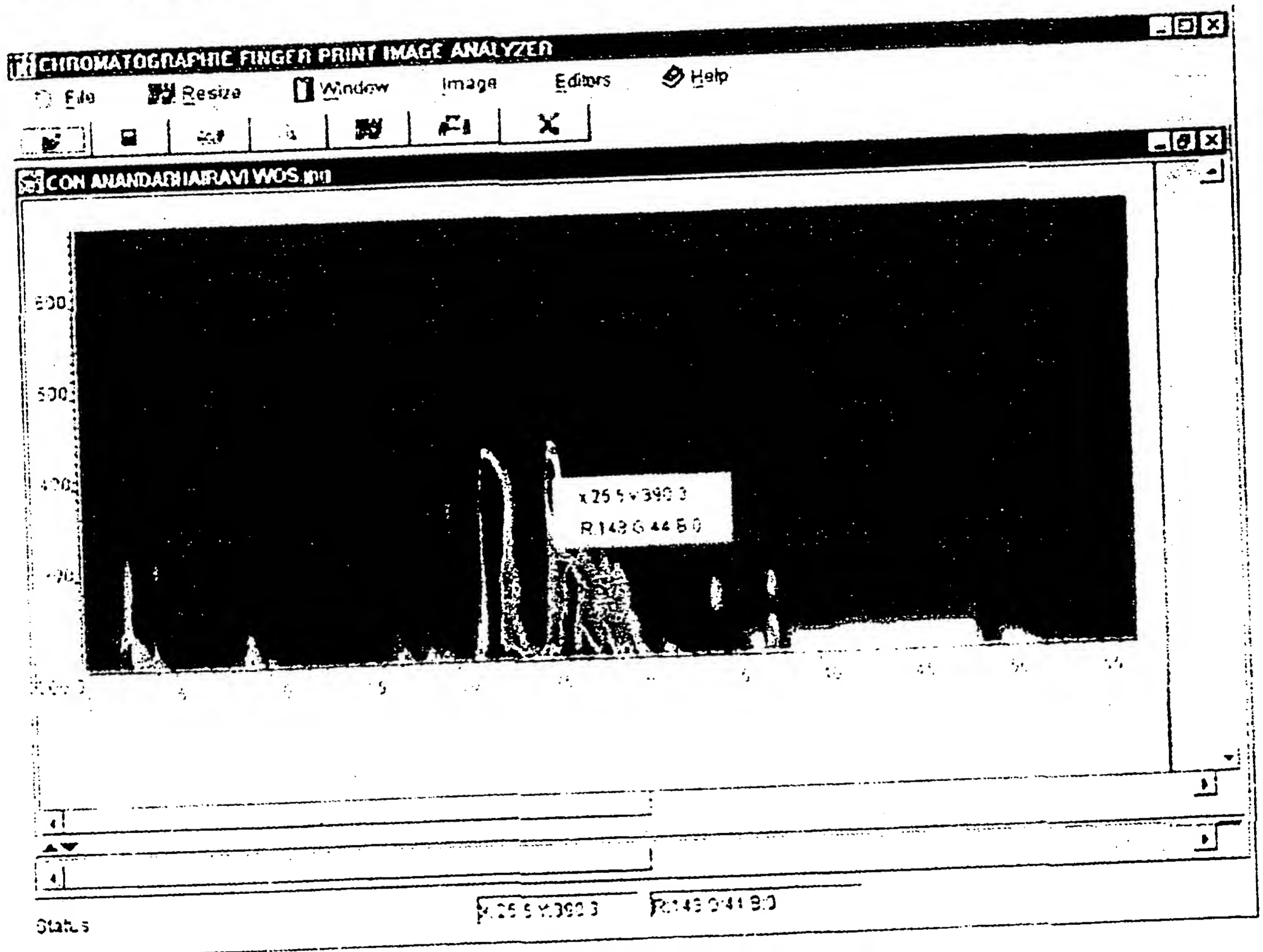
Figure 28

~~THE FINGER PRINTS OF THE SAME HERBAL PRODUCT IN DIFFERENT FORMS HELPS IN THE QUALITY CONTROL OF THE NATURAL SUBSTANCES. THE COMBINATION PEAKS AT 20 MIN IN NATURAL AND COMMERCIAL PRODUCTS INDICATES THE PRESENCE OF THE YELLOW COLORED MOLECULES IN ALL~~

## ANNOTATED MARKED-UP DRAWINGS

Figure 93

~~IMAGES WITH BAR CODE VALUES GIVEN BY THE SOFTWARE TO FEED FOR A BAR CODING SOFTWARE~~

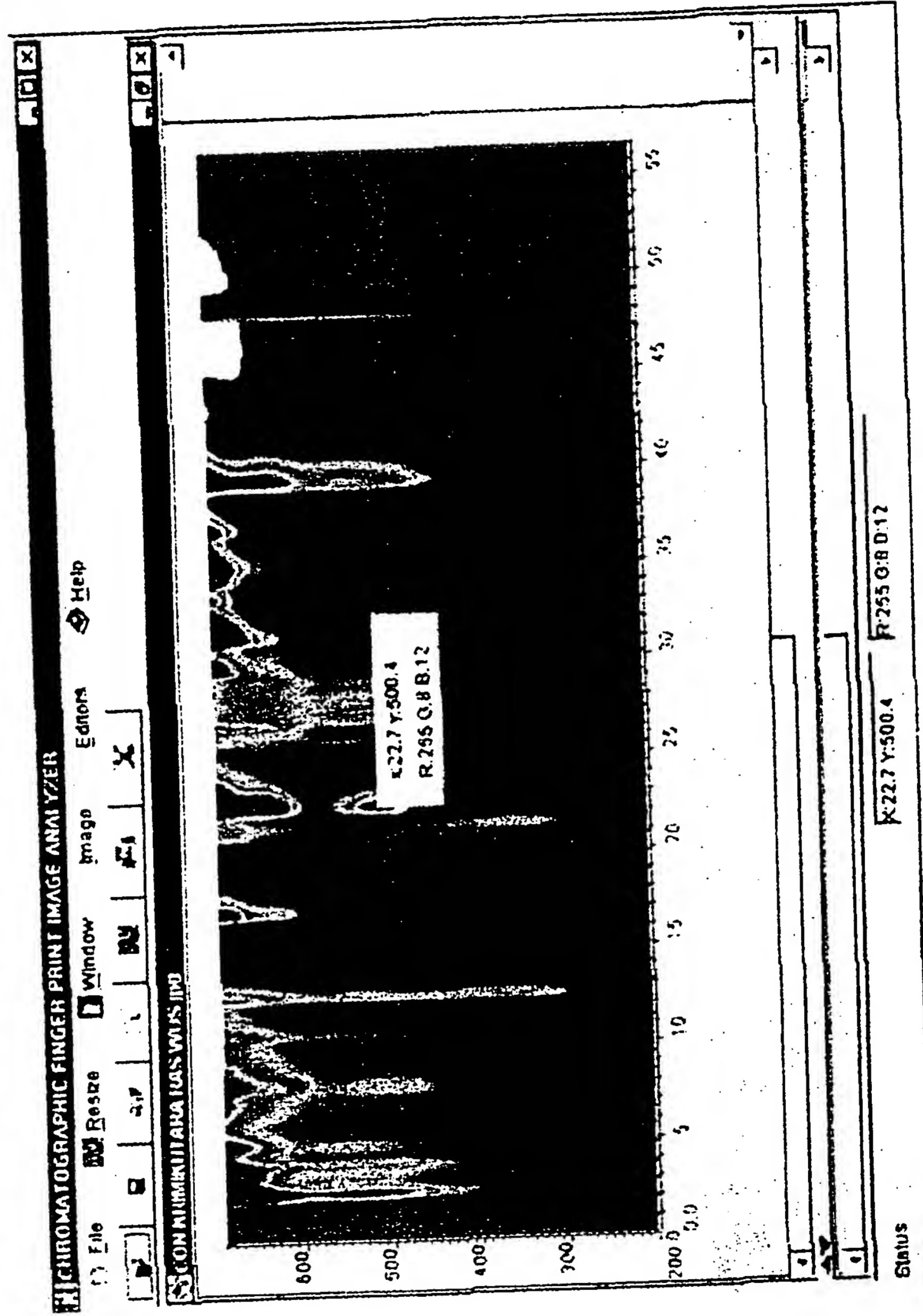


~~Anandabhairavi Ras~~

~~Y right clicking the image software is able to show the coordinates on the box near the peak. The same is shown in down tool bar. These will be exported to barcoding software which generates a barcode for the said values.~~

Figure 94

~~IMAGES WITH BAR CODE VALUES GIVEN BY THE  
SOFTWARE TO FEED FOR A BAR CODING SOFTWARE~~



~~Krimikutara Ras~~

~~Same mechanism as explained in Figure 93~~

Figure 95



X25.5Y390.3P148G44B0

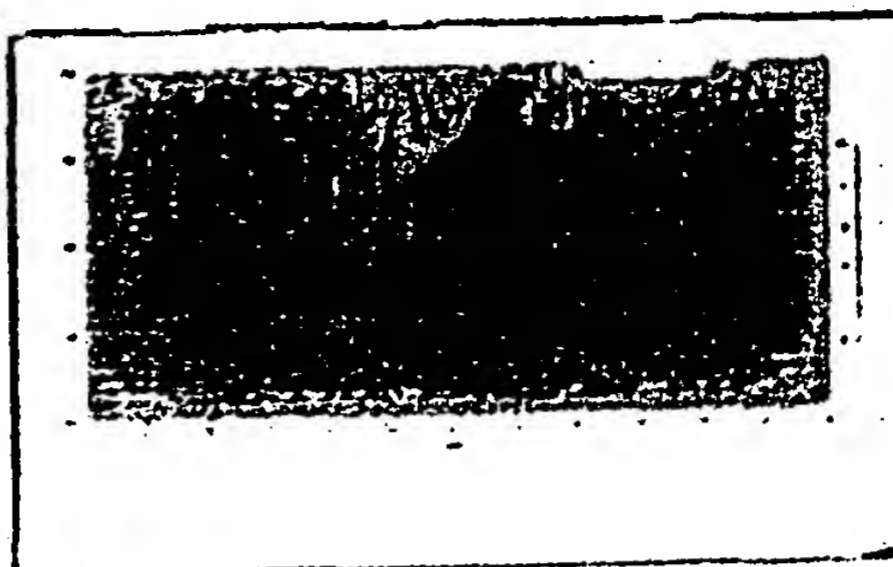
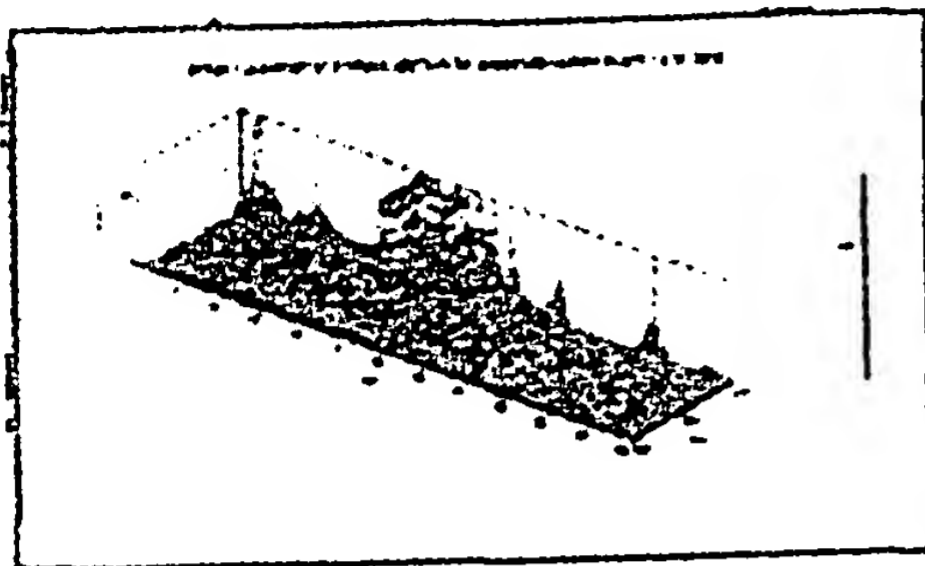
~~ANANDASHTHAKA VI RAS~~

~~Barcode generated for specified coordinates~~

**Name of the product: Anandabhairavi Ras**

**Owner: Industry**

**Finger prints:**



**Mfg. Date:**

**Date of expiry:**

**Individual constituents:**

**Batch number:**

**Lot number:**

**M.R.P.:**

**Dosage:**

**Precautions:**

**For Children:**

**For pregnant woman:**

**Barcode:**



X25.5Y390.3R148G44B0

ANANDABHAIRAVI

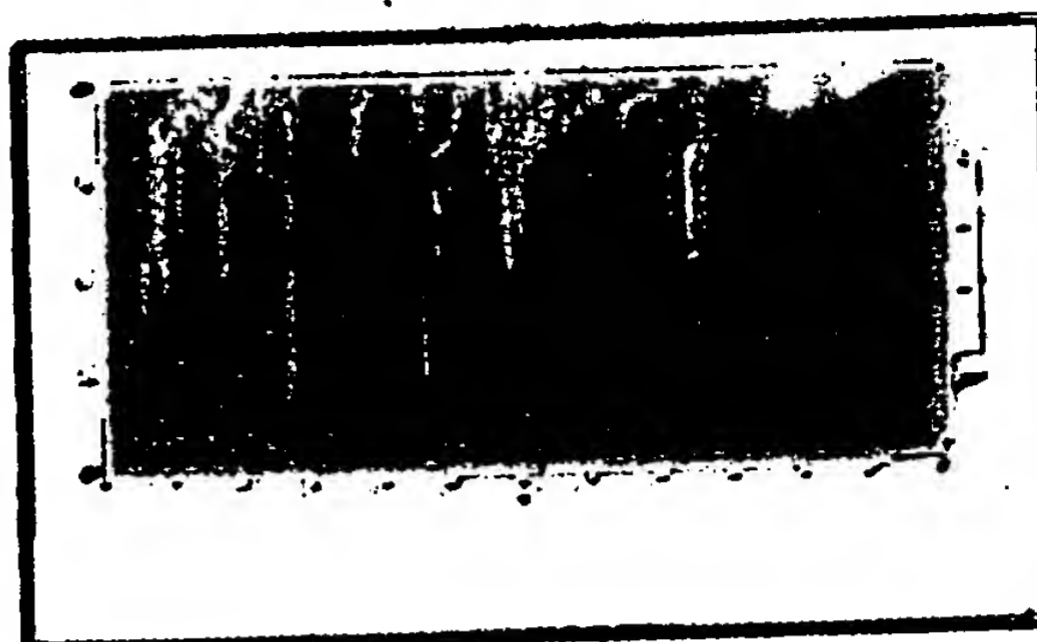
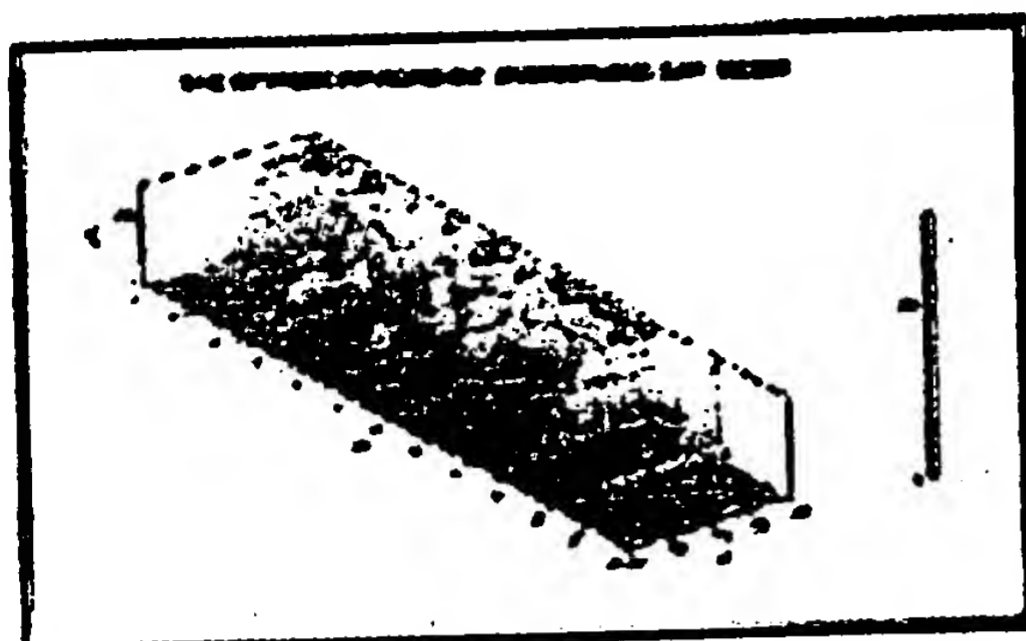
**Display Window For Anandabhairavi Ras**

~~Display windows for all the medicines will be done. This becomes a database for ERP CRM application.~~

Name of the product: Krimikutara Ras

Owner: Industry

Finger prints:



Mfg. Date:

Date of expiry:

Individual constituents:

Batch number:

Lot number:

M.R.P:

Dosage:

Precautions:

For Children:

For pregnant woman:

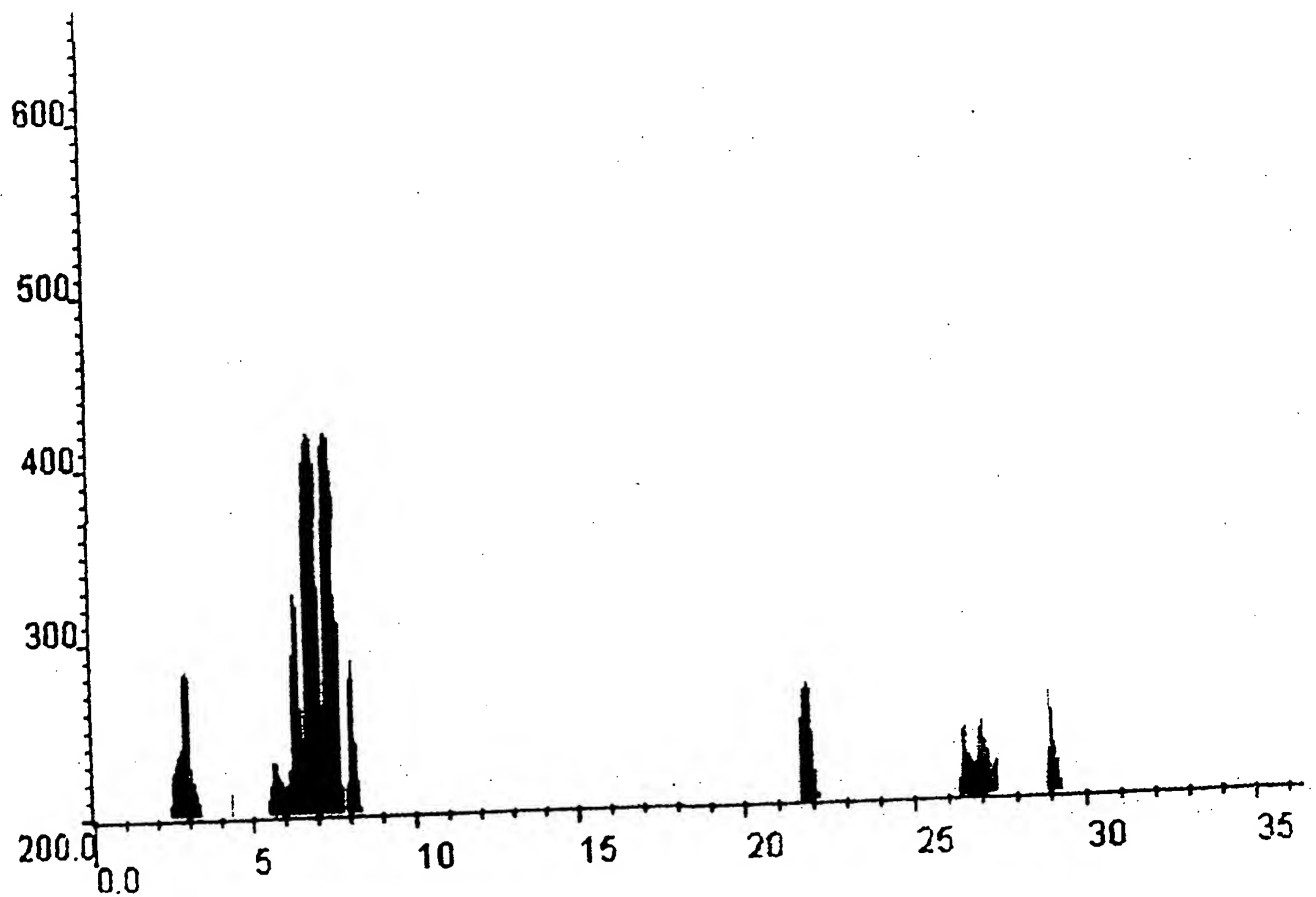
Barcode:



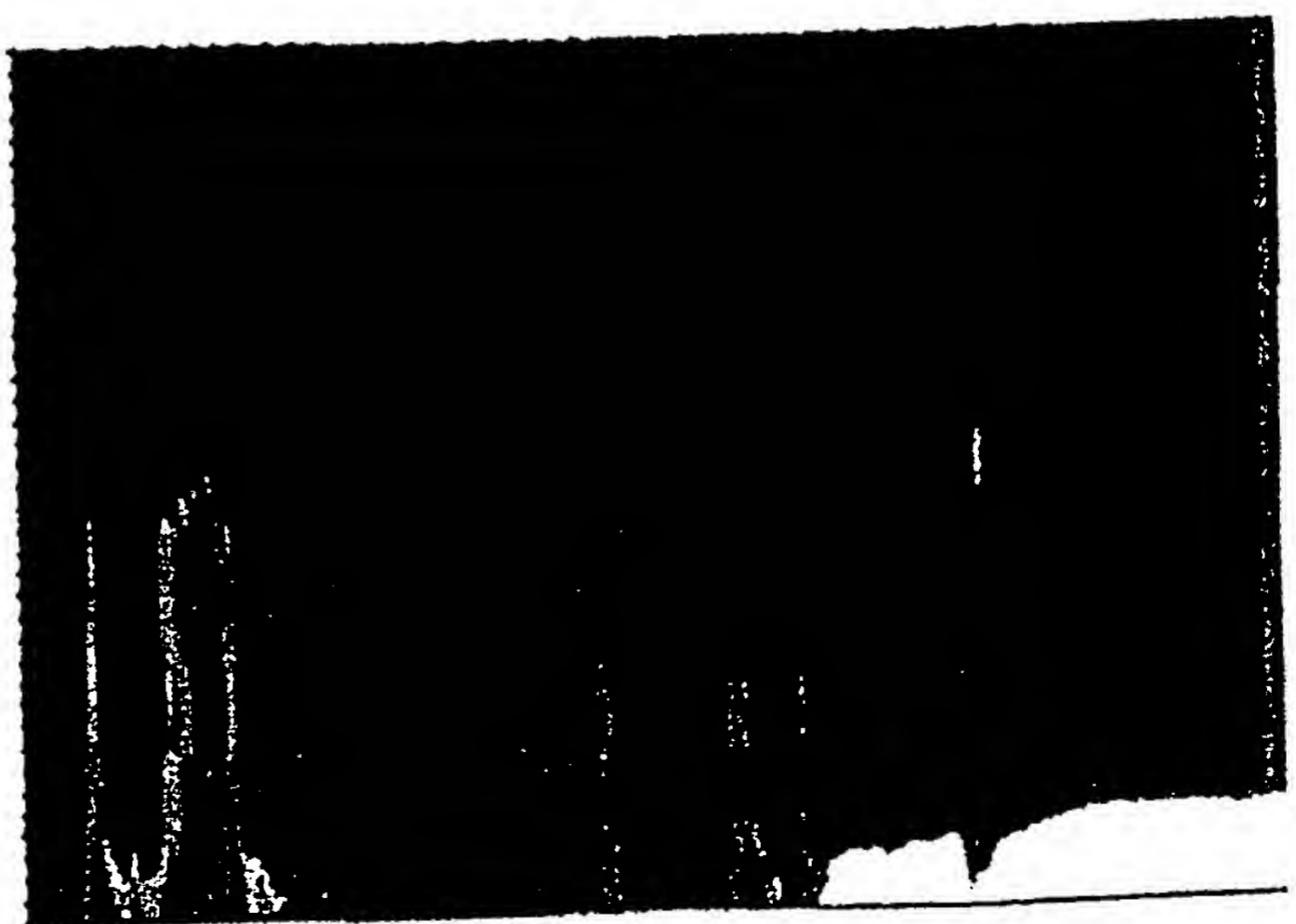
127.75500 482550817

KRIMIKUTARA RAS

~~Display Window For Krimikutara Ras~~



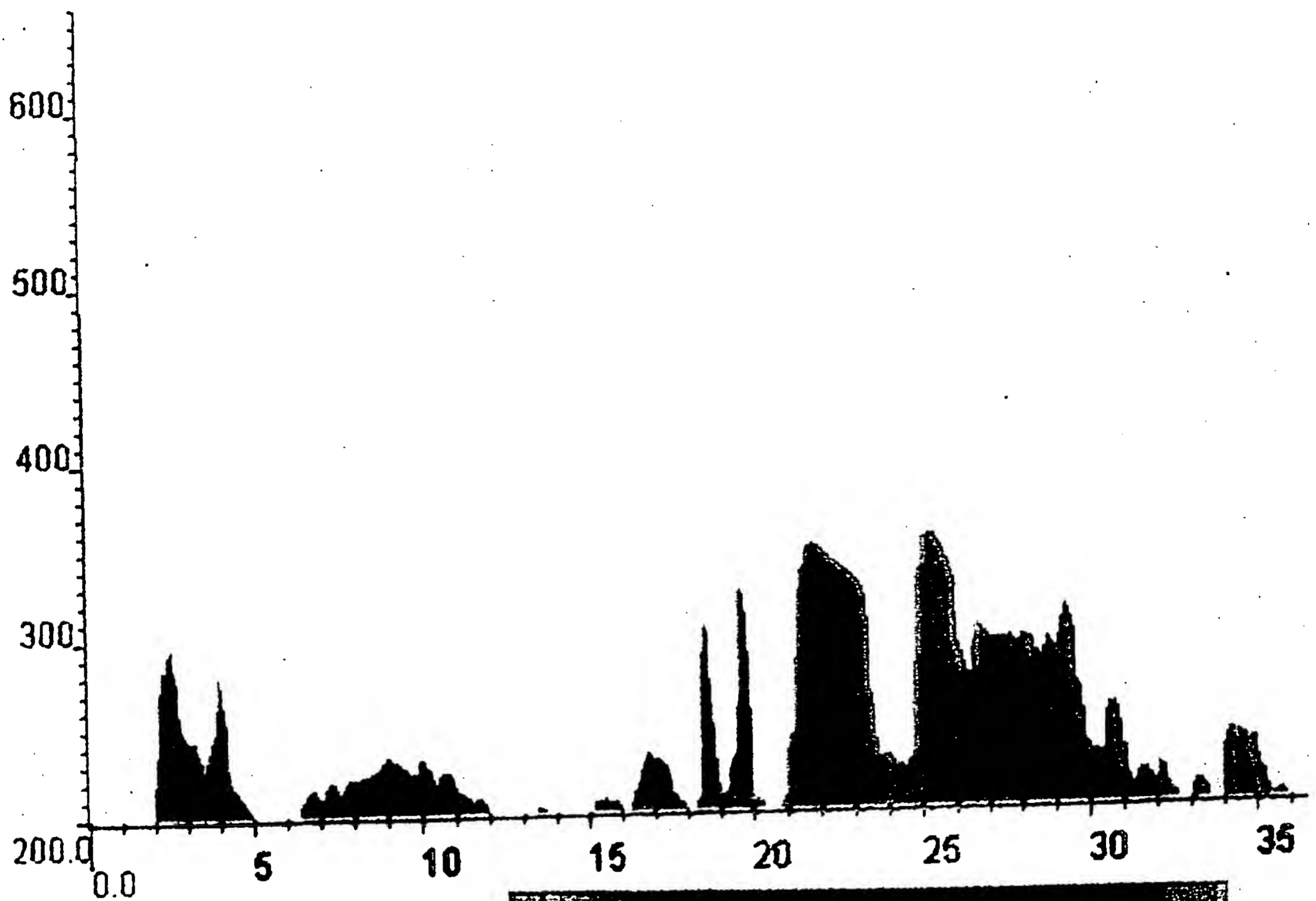
PeakNo	Area Of Pixels
1	271
2	8
3	1818
4	146
5	181
6	213
7	91



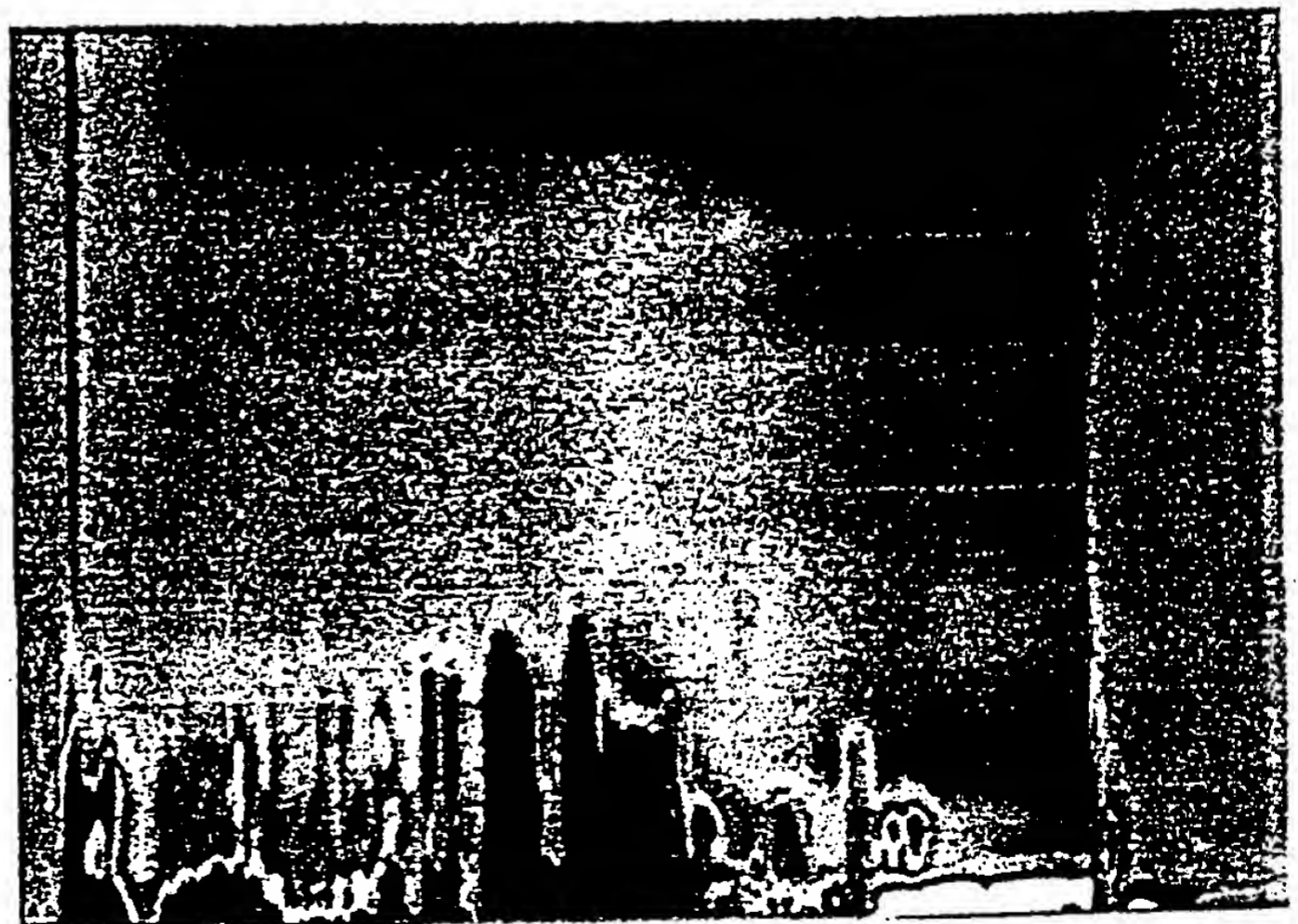
~~CHROMATOGRAM OF AZARDIRACTA INDICA~~  
~~(Tender leaves in February)~~

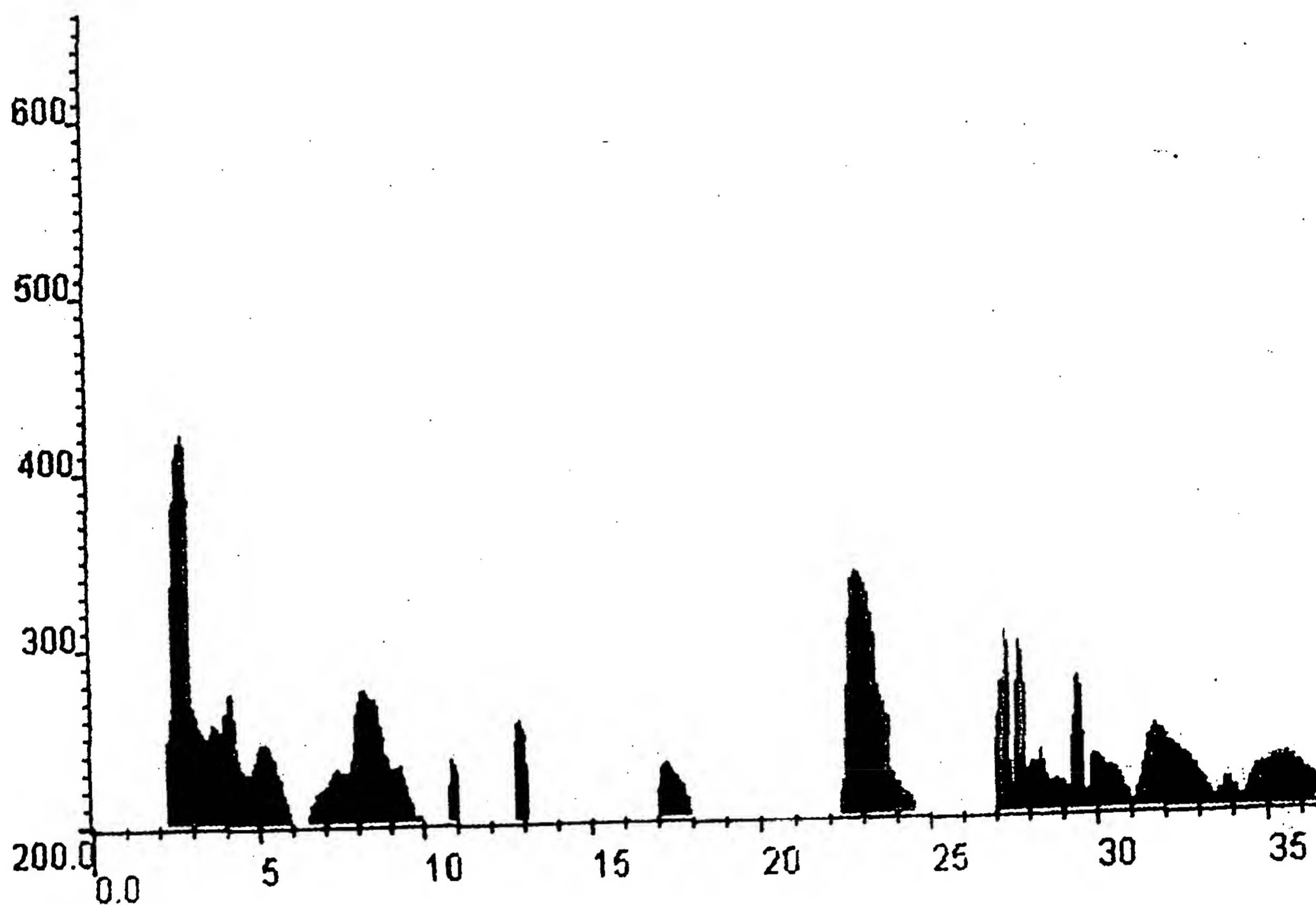
Figure 101

**ANNOTATED MARKED-UP DRAWINGS**



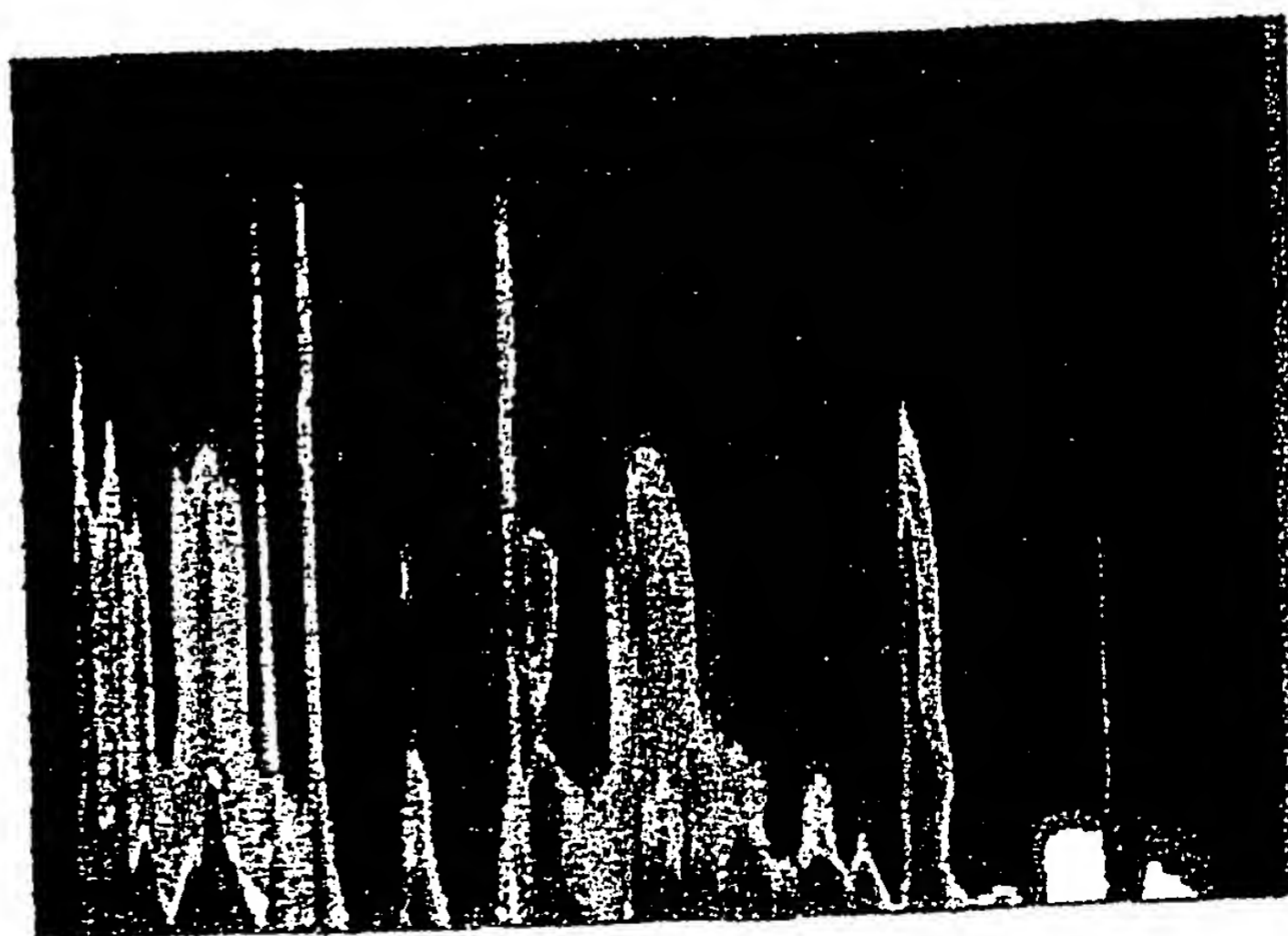
PeakNo	Area Of Pixels
1	1009
2	769
3	7
4	42
5	252
6	829
7	6984
8	35
9	322
10	12
11	405
12	9
13	59
14	106
15	8
16	31

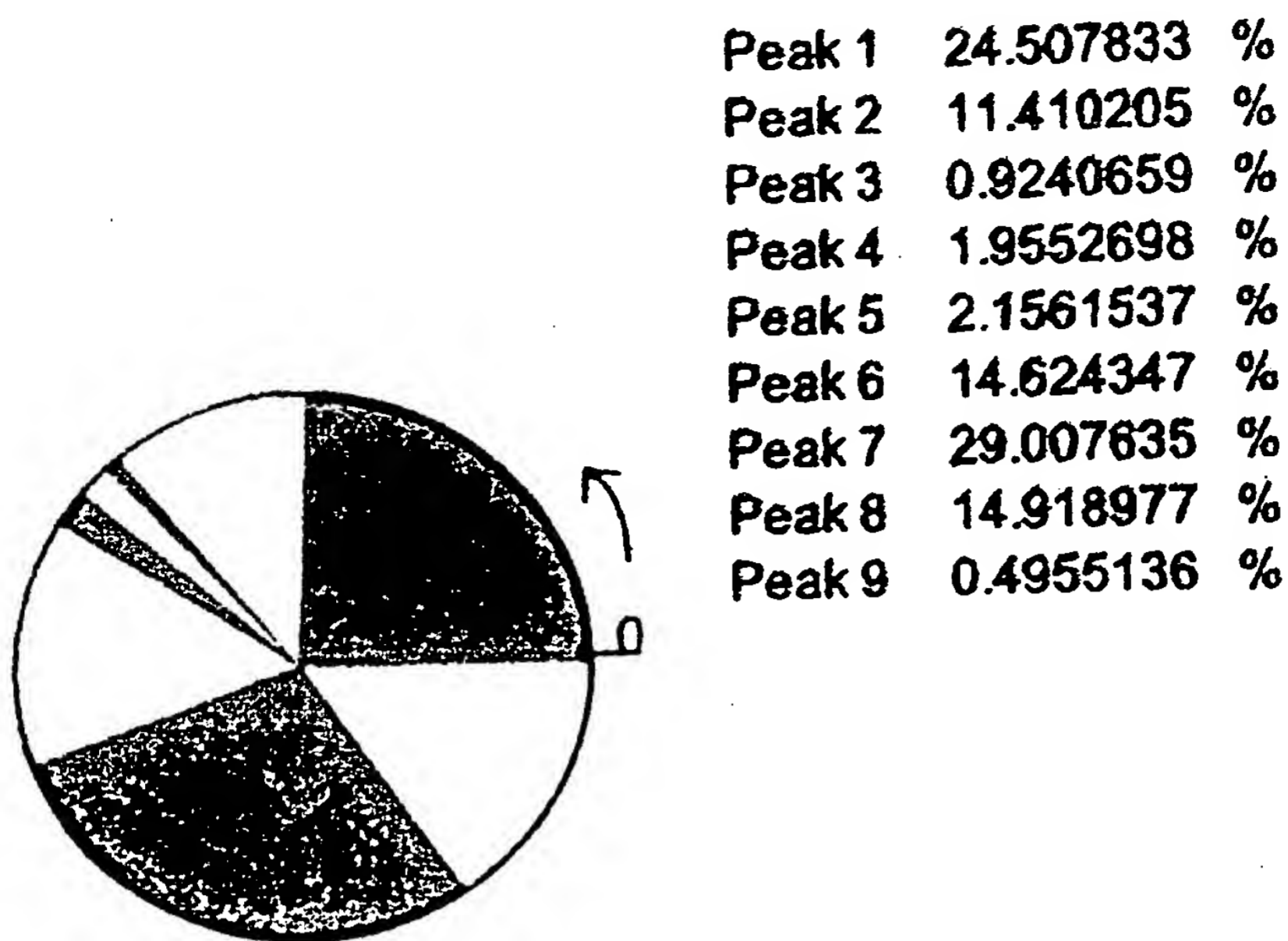




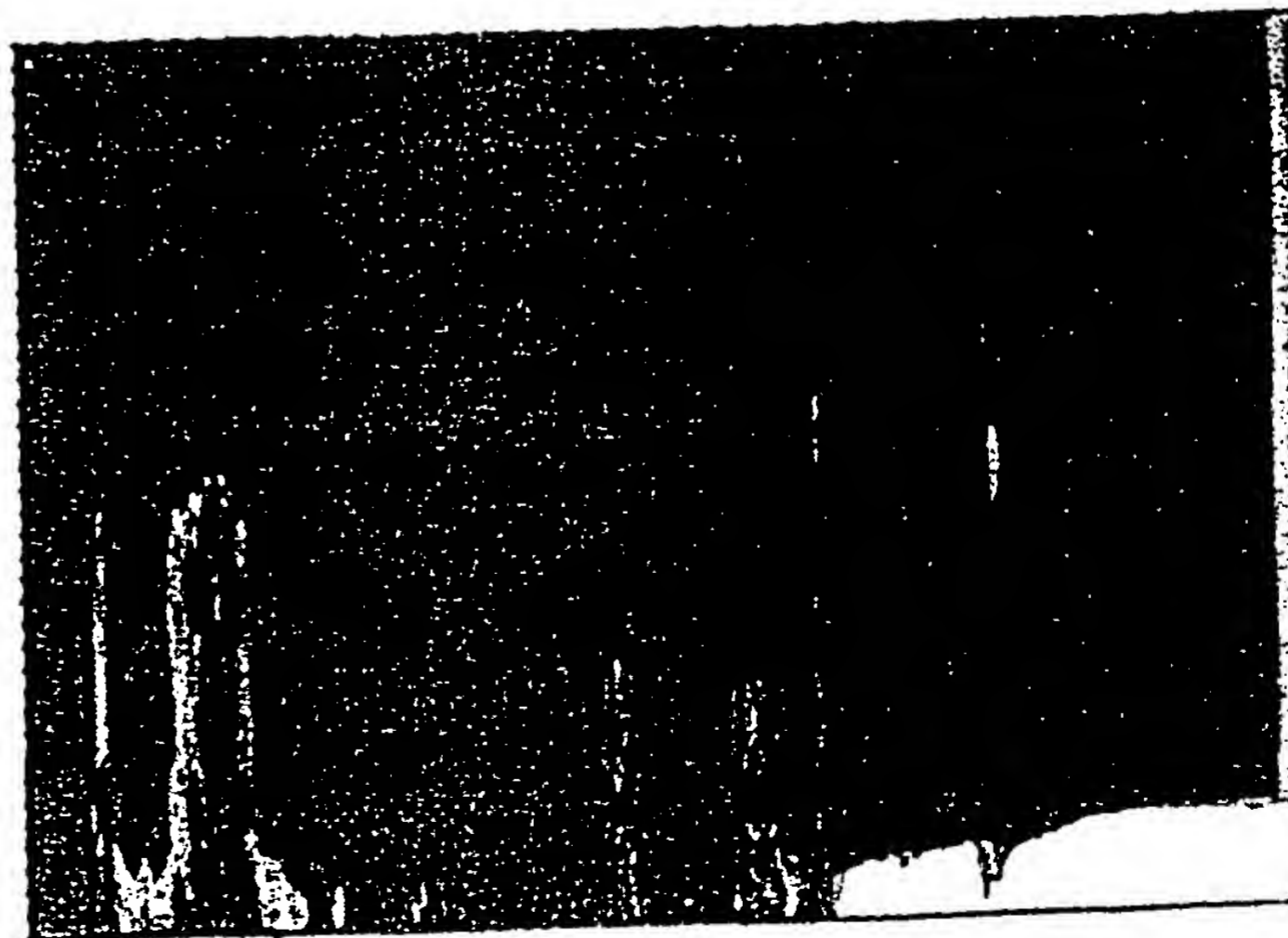
PeakNo      Area Of Pixels

1	1830
2	852
3	69
4	146
5	161
6	1092
7	2166
8	1114
9	37

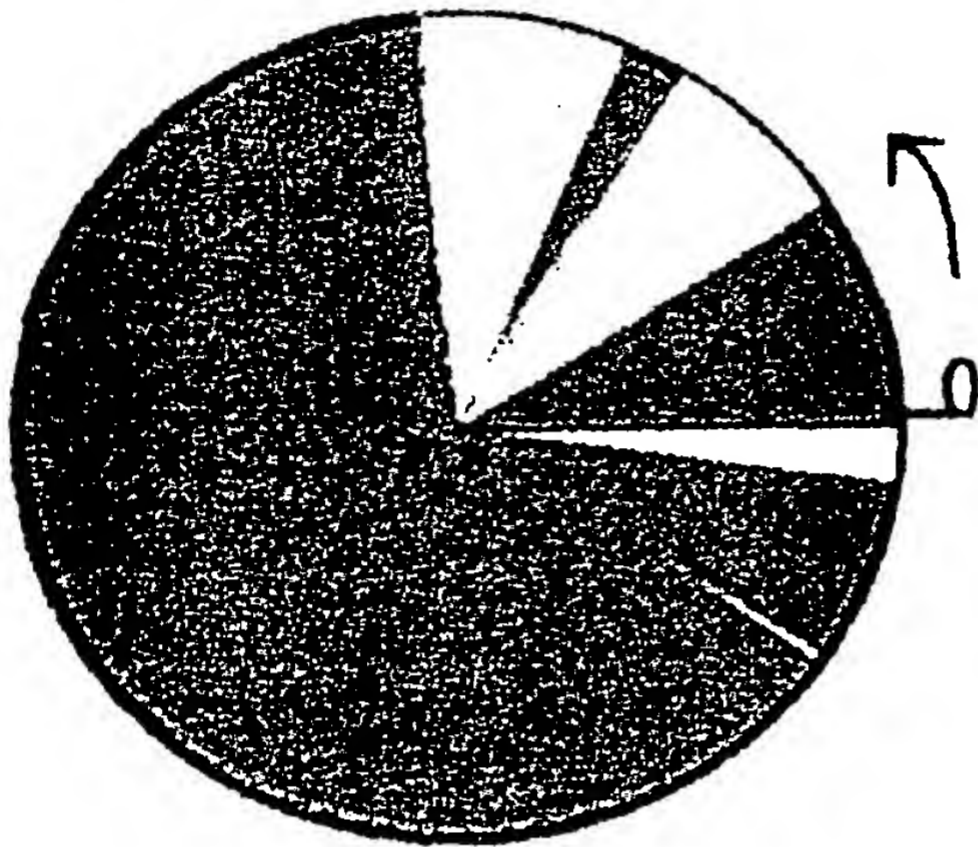




Percentage of pixels represents the constituents.



~~PIE DIAGRAM OF AZARDIRACTA INDICA~~  
~~(Tender leaves in February)~~



Peak 1	9.27475 %
Peak 2	7.0686646 %
Peak 3	0.06434415 %
Peak 4	0.3860649 %
Peak 5	2.3163893 %
Peak 6	7.620186 %
Peak 7	64.197075 %
Peak 8	0.32172075 %
Peak 9	2.9598308 %
Peak 10	0.11030425 %
Peak 11	3.7227685 %
Peak 12	0.08272819 %
Peak 13	0.54232925 %
Peak 14	0.97435427 %
Peak 15	0.07353617 %
Peak 16	0.28495267 %

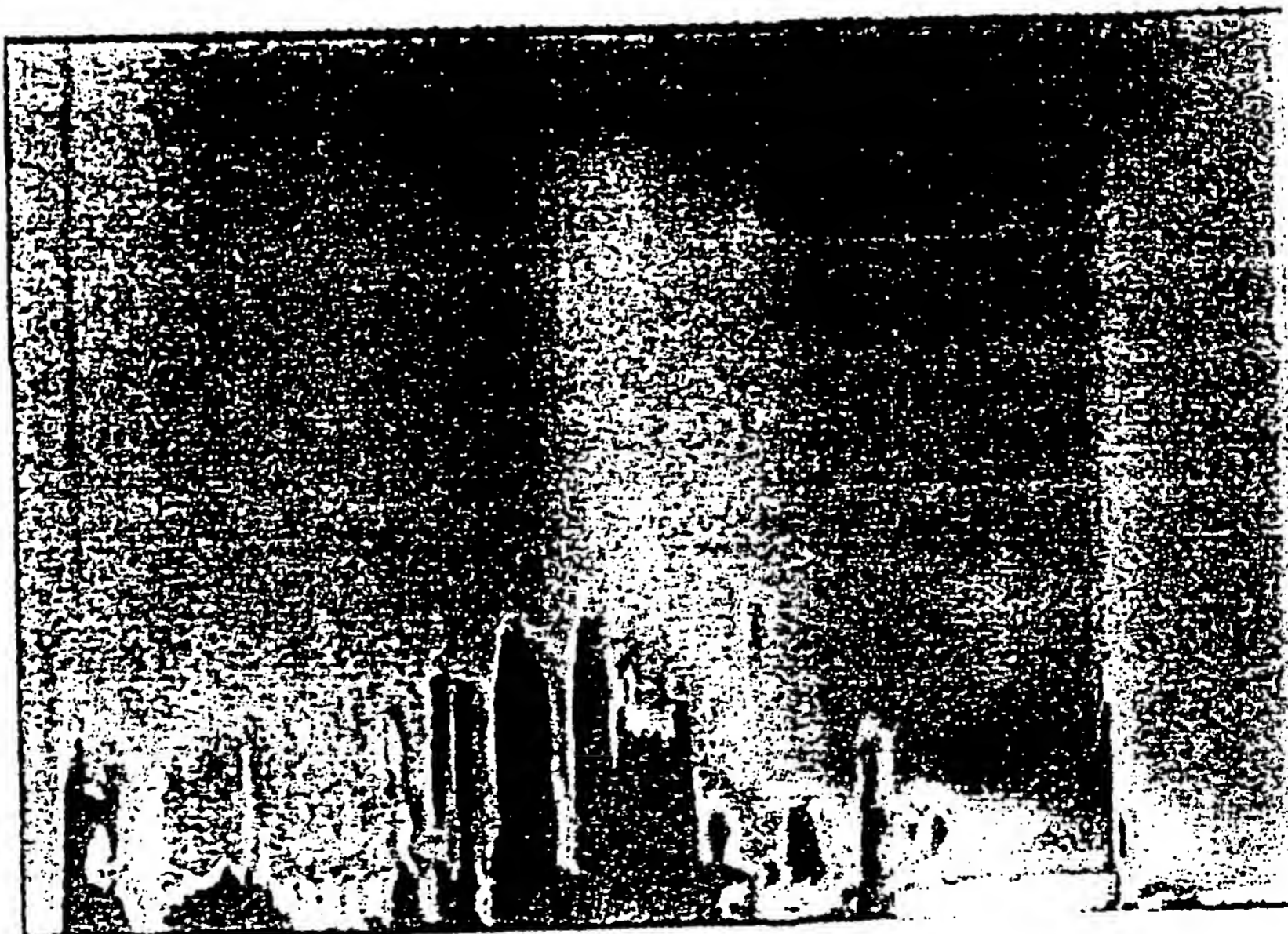
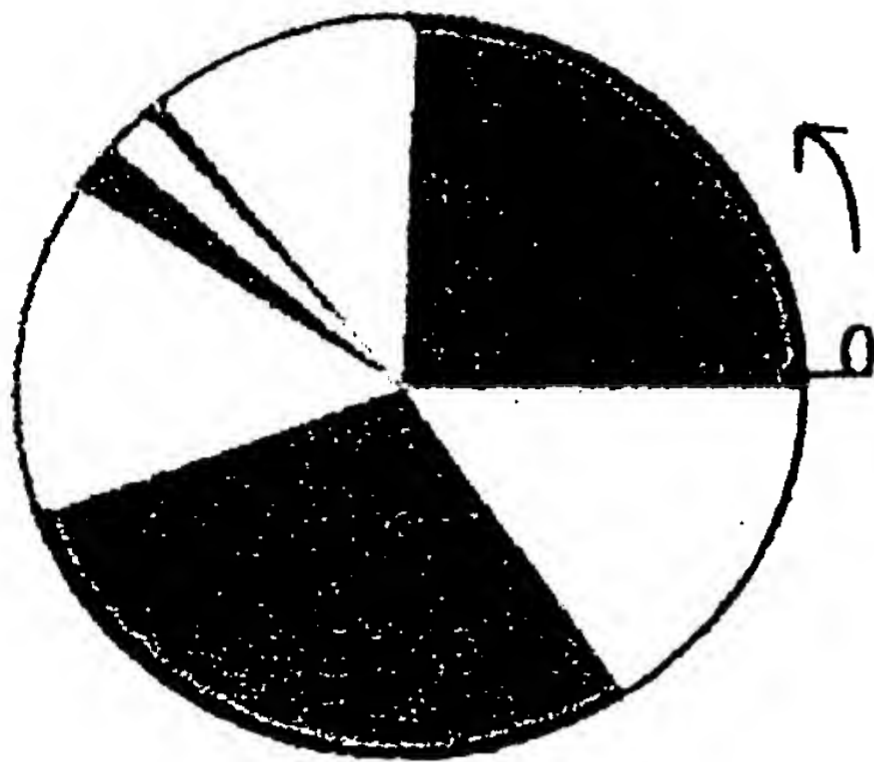


Figure 105

ANNOTATED MARKED-UP DRAWINGS



Peak 1	24.507833	%
Peak 2	11.410205	%
Peak 3	0.9240659	%
Peak 4	1.9552698	%
Peak 5	2.1561537	%
Peak 6	14.624347	%
Peak 7	29.007635	%
Peak 8	14.918977	%
Peak 9	0.4955136	%

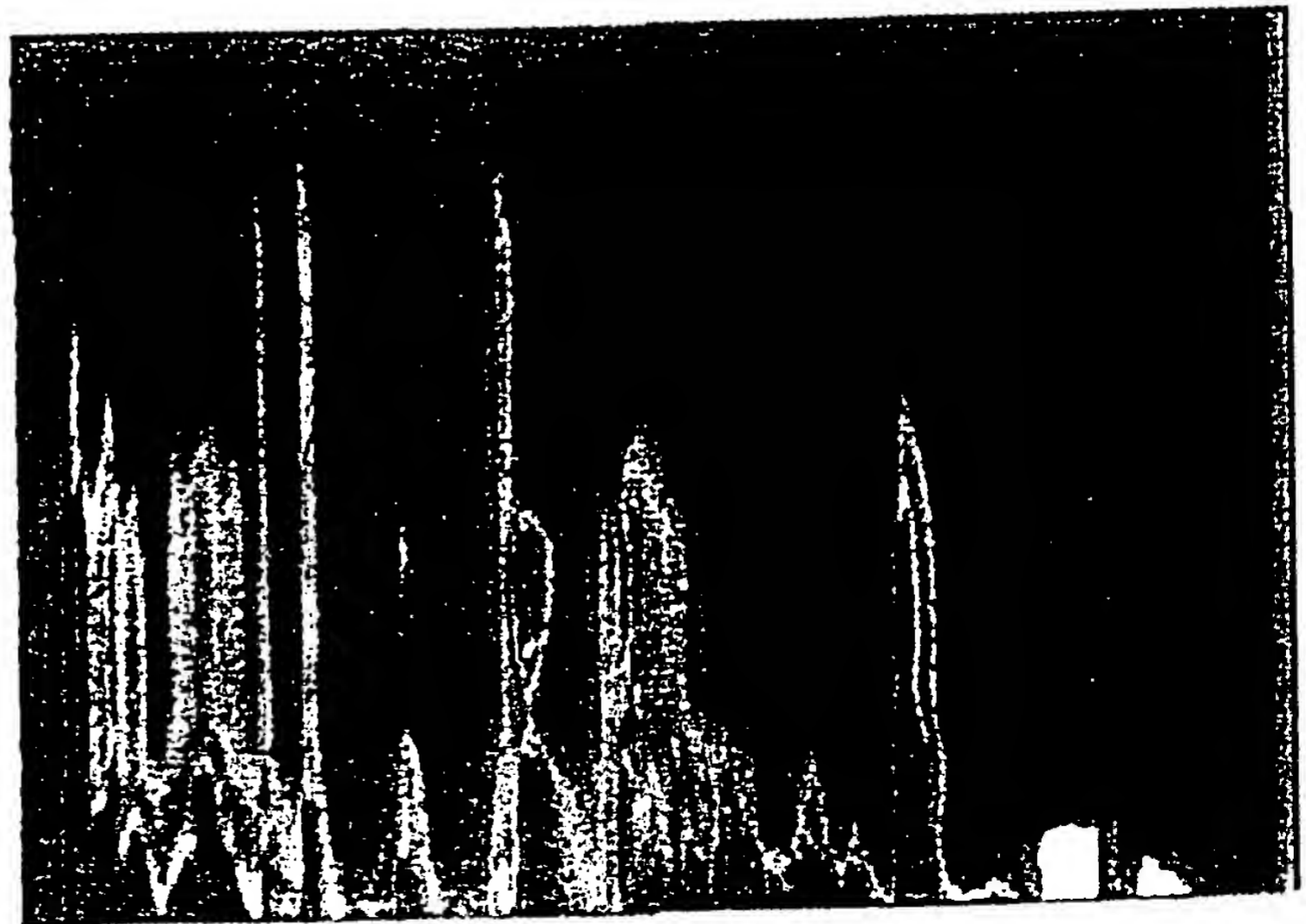
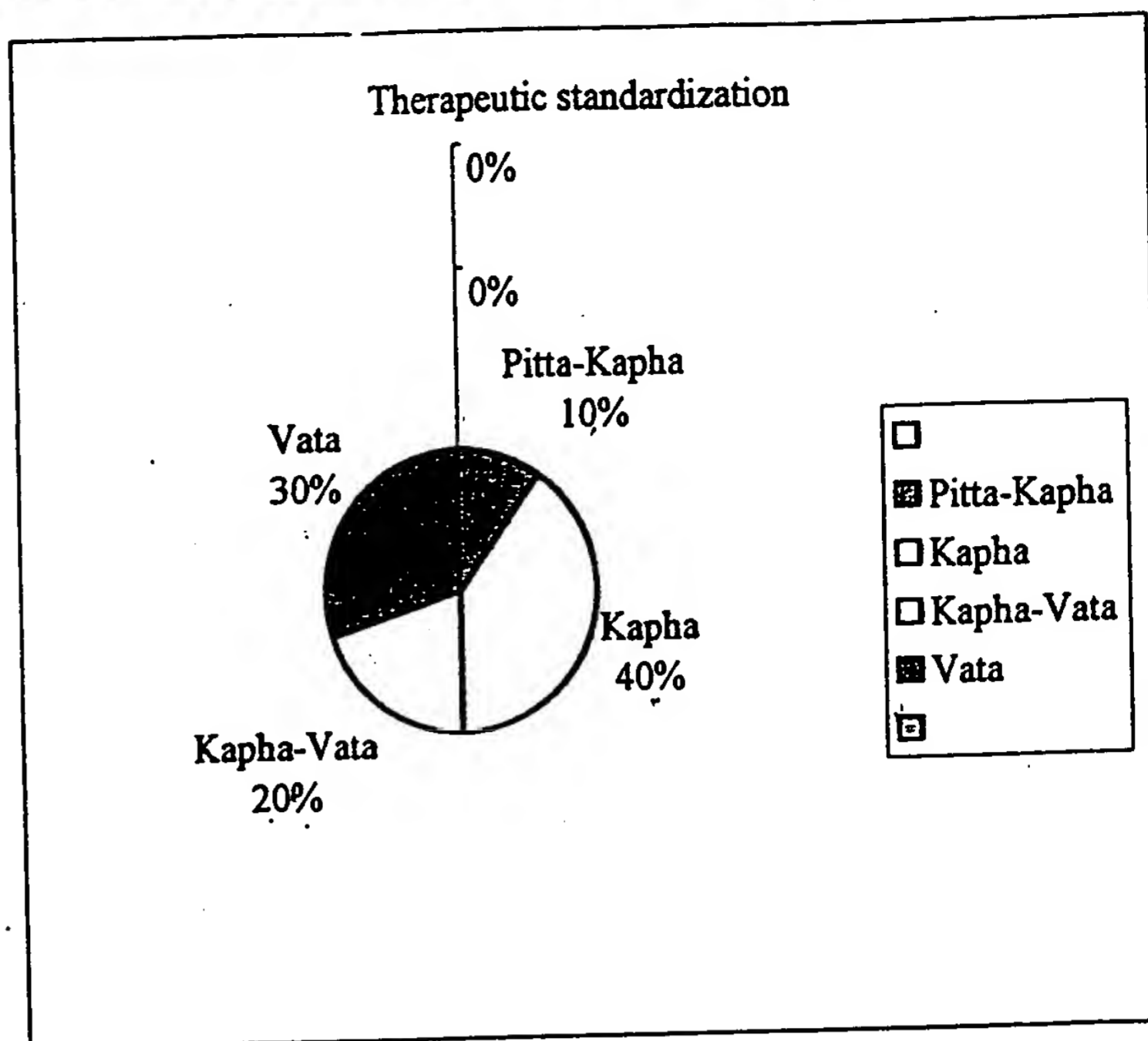


Figure 106

~~Pixel values or percentage values from graphs.~~

Pitta-Kapha: 10  
Kapha 40  
Kapha-Vat 20  
Vata 30

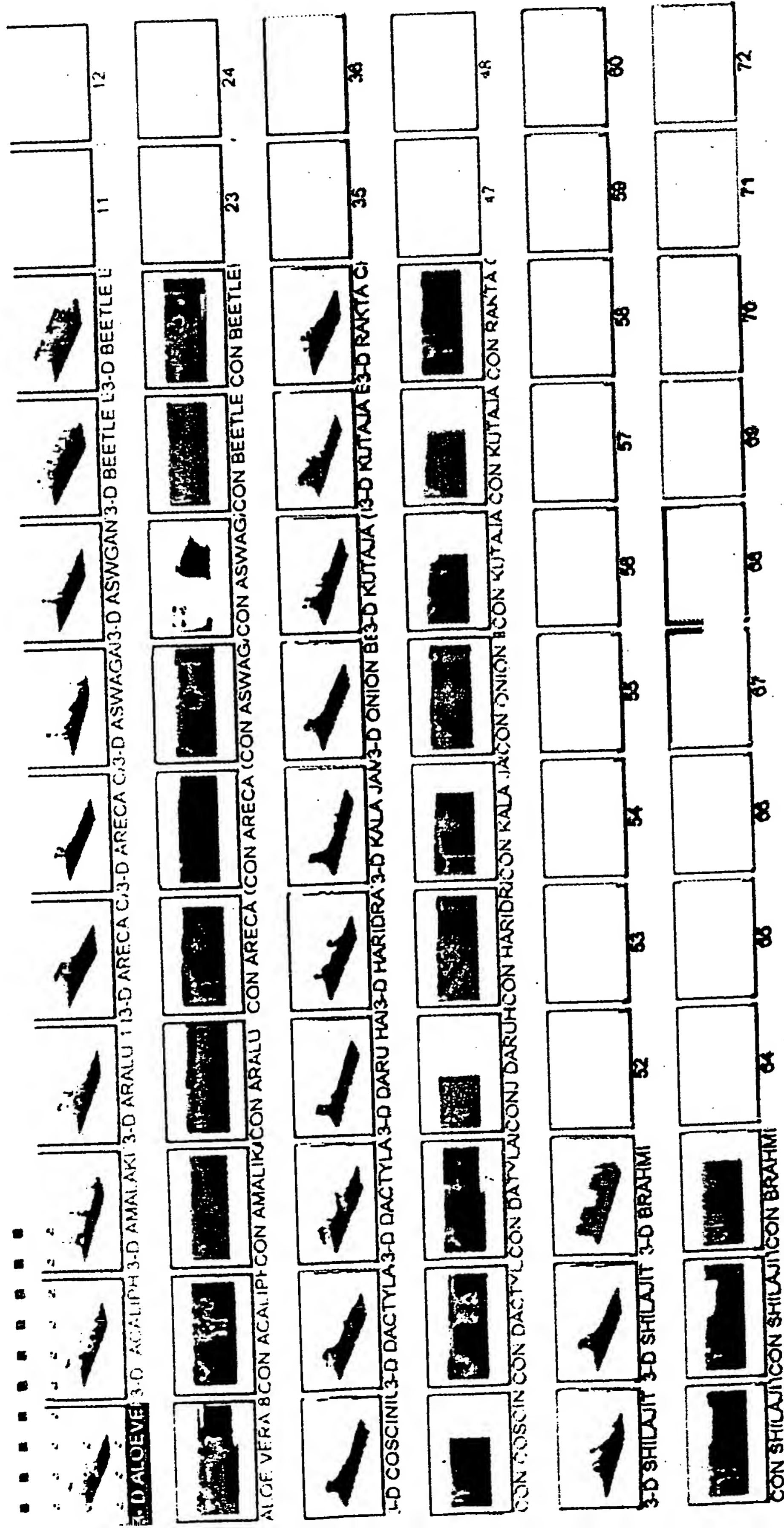


~~This gives the efficacy of the medicine due to the constituents present in various zones of the fingerprint.~~

~~The values of pixels were taken generally and are not for a chromatogram. This figure only shows only how it appears.~~

C:\WINDOWS\DESKTOP\Director files\SINGLE PLANTS

Figure 109



These libraries of 3d and contour images of medicines will be prepared as a database for various ERP and CRM applications. The 3d and Contour chromatograms are given in top and bottom times.

Databases based on color, taste, odour, therapeutic value, pharmacological parameters can be prepared to understand the medicinal efficacy of a specific herb/animal.

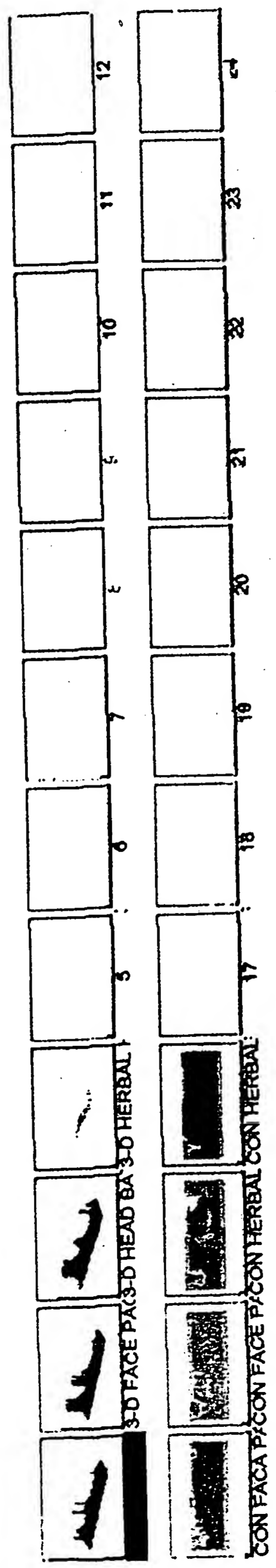


Fri, Sep 22, 2000

C:\WINDOWS\DESKTOP\Director files\COMMERCIAL SAMPLES

.....

Figure 111

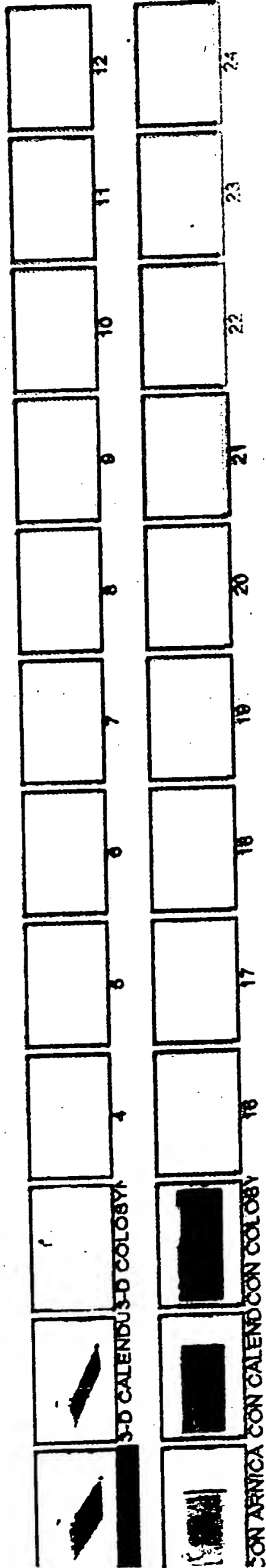


Example for adulterated cosmetic samples.

ANNOTATED MARKED-UP DRAWINGS

• • •  
• • •

Figure 112

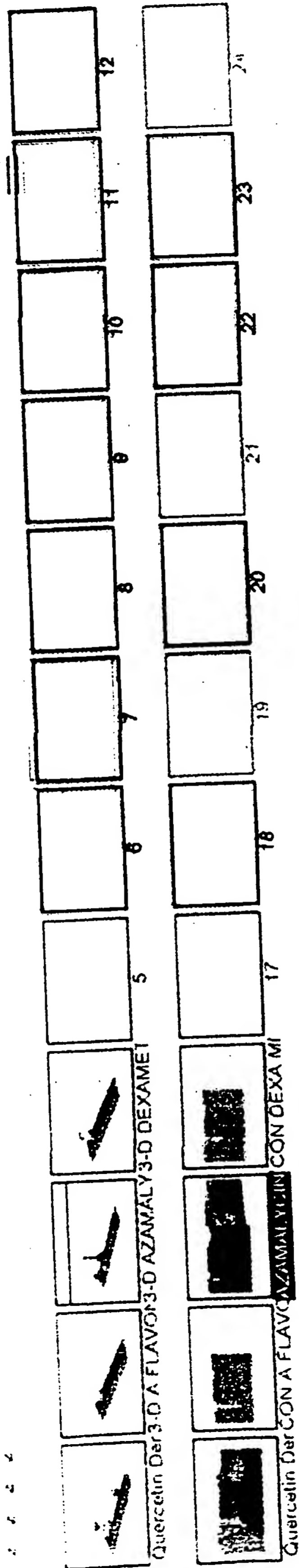


~~The fingerprint of Mother thistle only were done. They can be done to the level of  
femto gram level as the PDA detectors are very sensitive. Hence ditution can also be  
fingerprinted~~

Fri, Sep 22, 2000

# ANNOTATED MARKED-UP DRAWINGS

C:\WINDOWS\DESKTOP\Director files\ISO / TED COMPOUNDS  
Figure 113



~~This helps to know the purity after isolation and to know the UV spectrum of an unknown molecule.~~

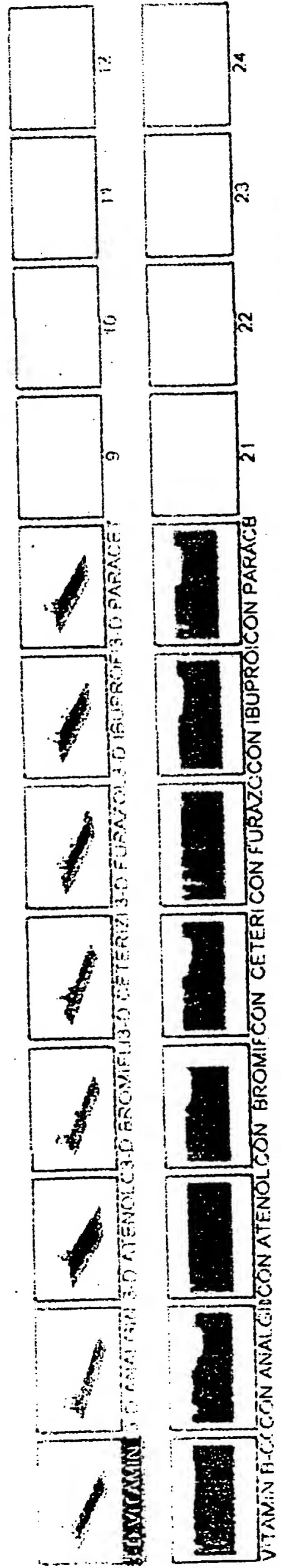
Fri, Sep 22, 200

ANNOTATED MARKED-UP DRAWINGS

C:\WINDOWS\DESKTOP\Director files\ALLOPATHIC MEDICINES

.....  
.....

Figure 114



~~This method can be used for all allopathic medicines for chemical and therapeutic standardization.~~

Figure 115

